NELAC Quality Systems Checklist

Organization Name:_____

Address (Mailing): _____

Address: _____

(Physical location): _____

Telephone: _____ Facsimile: _____

E-mail: _____ Other: _____

Personnel Interviewed:

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

Audit Location (If different): _____

Audit Date: _____

Audit Organization: _____

Auditor(s): _____ _____
(Signatures)

_____ _____ _____

Receipt acknowledgment by Laboratory: _____

☺ **Director --** 😐 **QA Officer --** ☹ **Analyst & Technical Personnel**

☯ **Application Review, Quality System Documents, Analytical SOP Reviews**

📂 **Records Review --** ✈ **Tour of Facility/ Direct Observation**

📑 **Final Report(s) of Results --** ♋**:..** / 🔔**:..** **QS/SOP References**

☑ **Outcome Based**

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.4 ORGANIZATION AND MANAGEMENT					
5.4.1 Is the laboratory legally identifiable? Document examined: [ ] Federal employee identification number [ ] Federal tax identification number [ ] Incorporation statement [ ] Town charter [ ] State Certificate of Existence [ ] Annual Report to the Secretary of State [ ] Business license [ ] Other _____	☯				
5.4.1 Is the laboratory organized and operated in such a way that its permanent, temporary and mobile facilities meet the requirements of Chapter 5 of the NELAC standards?	☺ ☑				
5.4.2.a Does the laboratory have a managerial staff with the authority and resources needed to discharge their duties?	☺ ☑				🔔
5.4.2.b Does the laboratory have processes to ensure its personnel are free from any commercial, financial and other undue pressures, which might adversely affect the quality of the work?	☯ ☺ 😐 ☹				♋
5.4.2.c Is the laboratory organized in such a way that confidence in its independence of judgment and integrity is maintained at all times?	☺ 😐 ☹ ☑				
5.4.2.d, 5.4.2.d.2, 5.5.2.e Does the laboratory specify and document the responsibility, authority, and interrelationship of all personnel who manage, perform or verify work affecting the quality of calibrations and tests using job descriptions for all positions? - Where is this information documented?	☯ ☺ 😐 📂				♋
5.4.2.d.1 Does the documentation clearly describe the lines of responsibility in the laboratory and shall be proportioned such that adequate supervision is ensured?	📂				♋
5.4.2.e, 5.6.2.e Is supervision provided by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test, and the assessment of the results?	☺ 😐				🔔
5.4.2.d.1, 5.4.2.e Is the ratio of supervisory to non-supervisory personnel such that there is adequate supervision to ensure adherence to laboratory procedures and accepted techniques? - What is the ratio of supervisory to non-supervisory personnel in each department?	☺ 😐 ☑				

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.4.2.f Does the laboratory have documented certifications that personnel performing all tests for which the laboratory is accredited have the appropriate educational and/or technical backgrounds? (Transcripts, copies of certificates, etc.)					
5.4.2.f Do the technical director(s) (however named) have overall responsibility for the technical operation of the environmental testing laboratory?					
5.4.2.f, 4.1.1.1.a Do the technical director(s) of a laboratory engaged in chemical analyses have a bachelors degree in chemical, environmental, biological sciences, physical sciences or engineering, with at least 24 college semester credit hours in chemistry and at least 2 years of experience in analyses for which accreditation is sought? (A masters or doctoral degree may be substituted for 1 year experience)					
5.4.2.f, 4.1.1.1.b Do the technical director(s) of a laboratory limited to inorganic chemical analyses, other than metals analysis, have at least an earned associates degree in chemical, environmental or physical sciences or 2 years equivalent and successful college education, with at least 16 college semester credit hours in chemistry and at least 2 years of experience in analyses for which accreditation is sought?					
5.4.2.f, 4.1.1.1.c Do the technical director(s) of a laboratory engaged in microbiological or biological analyses have a bachelors degree in microbiology, biology, chemical, environmental sciences, physical sciences or engineering, with at least 16 college semester credit hours in general microbiology and biology and at least 2 years of experience in analyses for which accreditation is sought? (A masters or doctoral degree may be substituted for 1 year experience)					
5.4.2.f, 4.1.1.1.c Do the technical director(s) of a laboratory engaged in microbiological analyses limited to fecal coliform, total coliform, and standard plate count have at least an associates degree in an appropriate field of the sciences or applied sciences with 4 college semester credit hours in general microbiology and one year experience in environmental analyses. (Two years of equivalent and successful college education including the microbiology requirement may be substituted for an associates degree).					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.4.2.f, 4.1.1.1.d Do the technical director(s) of a laboratory engaged <u>in radiological analyses</u> have a bachelors degree in chemistry, physics or engineering, with at least 24 college semester credit hours in chemistry and at least 2 years of experience in the radiological analyses of environmental samples? (A masters or doctoral degree may be substituted for 1 year experience)	☯				♋
5.4.2.g Does the quality assurance officer (however named) have responsibility for the quality system and its implementation?	☯ ☺ 😐				♋
5.4.2.g Does the QA officer have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical director? (QA officer may also be the technical director or deputy technical director when staff is limited).	☺ 😐				🔔
5.4.2.g.1 Does the QA officer serve as the focal point for QA/QC? - How is the review/oversight of QC data handled? Who is responsible for this?	☺ 😐 📂				🔔
5.4.2.g.1 Is the QA officer responsible for the oversight and/or review of quality control data?	☺ 😐 📂				🔔
5.4.2.g.2 Are the QA officer functions independent from laboratory operations where QA oversight is provided?	☺ 😐 📂				🔔
5.4.2.g.3 Is the QA officer able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence?	😐 📂				🔔
5.4.2.g.4 Does the QA officer have documented training and/or experience in QA/QC procedures? - What training/experience is QA/QC procedures does the QAO have? How is this documented?	😐 📂				🔔
5.4.2.g.4 Is the QA officer knowledgeable in the quality system as defined under NELAC?	😐 📂				🔔
5.4.2.g.5 Does the QA officer have a general knowledge of the analytical test methods for which data review is performed? - How knowledgeable is the QAO in the analytical test methods?)	😐 📂				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.4.2.g.6, 5.4.2.g.7, 5.5.3.1 Does the QA officer: [ ] arrange for or conduct internal audits on the entire technical operation annually to verify that its operations continue to comply with the requirements of the laboratory's quality system, and [ ] notify laboratory management of deficiencies in the quality system and monitor corrective action?	☺ 😐 📂				🔔
5.4.2.h Does the laboratory nominate deputies in the case of absence of the technical director(s) and/or QA officer? - Who are the nominated deputies?	☺ 😐 📂				🔔
5.4.2.j, 2.2.3, 2.4.1 Does the laboratory perform proficiency testing two times per year per analyte per matrix per program from a NELAC approved provider? - Can we take a look at the raw data and bench sheets for the last two PT rounds or one WS round and one WP round? See 5.12.3	☺ 😐 📂				🔔
5.5 QUALITY SYSTEM					
5.5.1.b, 5.5.1.d Is the quality documentation available to, understood by, and implemented by all laboratory personnel?	☺				🔔
5.5.1.e Does the QA officer keep the quality manual current? - Who is responsible for keeping the QAM current?	☺ 😐				🔔
5.5.1.a, 5.5.2 Does the quality manual and related quality documentation state the laboratory's policies and procedures that were established in order to meet the requirements of the NELAC standards?	☯				♋
5.5.2, 5.5.2.f Does the quality manual title page list the following: a.___ Document title b. ___ Laboratory's full name and address c.___ The name, signature, title, address (if different from above), and telephone number of individual(s) responsible for the laboratory; d.___ The name and signature of the quality assurance officer (however named) e.___ The identification of all major organizational units covered by this quality manual f.___ Effective date of the version	☯				♋
5.5.2.a, 5.5.1.c Does the quality manual and related quality documentation include the objectives and commitments by top management?	☯				♋

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.5.2.b Does the quality manual and related quality documentation include the organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts?	☯				☺
5.5.2.d Does the quality manual and related quality documentation include procedures to ensure that all records required under NELAC are retained?	☯				☺
5.5.2.d Does the quality manual and related quality documentation include procedures for control and maintenance of documentation through a document control system which ensures that all SOPs, manuals, or documents clearly indicate the time period during which the procedure or document was in force?	☯				☺
5.5.2.g Does the quality manual and related quality documentation include procedures for achieving traceability of measurements?	☯				☺
5.5.2.h Does the quality manual and related quality documentation include a list of all methods under which the laboratory performs its accredited testing?	☯				☺
5.5.2.i Does the quality manual and related quality documentation include mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work?	☯				☺
5.5.2.j Does the quality manual and related quality documentation include reference to the calibration and/or verification test procedures used?	☯				☺
5.5.2.k Does the quality manual and related quality documentation include procedures for handling submitted samples?	☯				☺
5.5.2.l Does the quality manual and related quality documentation include reference to the major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests?	☯				☺
5.5.2.m Does the quality manual and related quality documentation include reference to procedures for calibration, verification and maintenance of equipment?	☯				☺
5.5.2.n Does the quality manual and related quality documentation include reference to verification practices which may include inter-laboratory comparisons, proficiency testing programs, use of reference materials, and internal quality control schemes?	☯				☺

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.5.2.o Does the quality manual and related quality documentation include procedures to be followed for feedback and corrective action for failed quality control samples, or when departures from documented policies and procedures occur?	☯				☺
5.5.2.p Does the quality manual and related quality documentation include laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications?	☯				☺
5.5.2.q Does the laboratory have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities? - How are customer complaints handled?	☯				☺
5.4.2.i, 5.5.2.r Does the laboratory have documented policies and procedures to ensure the protection of clients' confidential information and proprietary rights? (This may not apply to in-house labs) - What policies are in place to protect client confidentiality?	☯				☺
5.5.2.s Does the laboratory have documented policy and procedures for audits and data review? - Who is involved in data review?	☯				☺
5.5.2.t Does the quality manual and related quality documentation include processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and/or receive any needed training?	☯				☺
5.5.2.u Does the quality manual and related quality documentation include an ethics policy statement developed by the laboratory and processes and procedures for educating and training personnel in their ethical and legal responsibilities including the potential punishments and penalties for improper, unethical, or illegal actions? - What elements of the ethics policy address laboratory specific processes?	☯				☺
5.5.2.v Does the quality manual and related quality documentation include reference to procedures for reporting analytical results?	☯				☺
5.5.2.w Does the quality manual and related quality documentation include a Table of Contents, and applicable lists of references and glossaries, and appendices?	☯				☺

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.5.2.c Does the quality manual and related quality documentation include the relationship between management, technical operations, support services and the quality system?	☯				♋
5.5.3.1 Does the quality assurance officer plan and organize audits as required by a predetermined schedule and requested by management? - What schedule is used for the internal audit?	☺ 😐 📂				🔔
5.5.3.1 Is the internal audit conducted by personnel trained and qualified as auditors who, wherever possible, are independent of the activities being audited? (Personnel should not audit their own activities except when it can be demonstrated that an effective audit will be carried out) - Who has the responsibility of performing the internal audit?	☺ 😐 📂				🔔
5.5.3.1 Is immediate corrective action taken when audit findings cast doubt on the correctness or validity of the calibrations or test results? - How are the findings made during the internal audit handled?	☺ 😐 📂				🔔
5.5.3.1 Are clients notified immediately, in writing, when their work is affected by the findings from an internal audit?	☺ 😐 📂				🔔
5.5.3.2 Does the laboratory have a procedure for the annual management review of the quality system? - Can you tell me who conducts the management review, who it is reported to, and what elements are included?	☯				♋
5.5.3.2 Is an annual review of the quality system completed by management to evaluate its continuing suitability and effectiveness and make any necessary changes or improvements?	☺ 📂				🔔
5.5.3.2 Does the annual review take into account: a.___ Reports from managerial and supervisory personnel, b.___ The outcome of recent internal audits, assessments by external bodies, c.___ The results of inter-laboratory comparisons or proficiency tests, d.___ Any changes in the volume and type of work undertaken, (What are the lab procedures for evaluating changes in the volume and type of work undertaken?) e.___ Feedback from clients, f.___ Corrective actions and other relevant factors?	☺ 📂				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.5.3.2 Does the laboratory maintain records of review findings and actions?	🗁				🔔
5.5.3.3 Are all audits and review findings and any corrective actions that arise from them documented? - Are corrective actions that are completed the same day, signed off as a closed CAR?	🗁				🔔
5.5.3.3 Does the laboratory management ensure that corrective actions arising from audit reviews are discharged within the agreed time frame as indicated in the quality manual and/or SOPs? - How does the laboratory identify an agreed time frame for the completion of a corrective action?	☺ 🗁				🔔
5.5.3.4 Does the laboratory ensure the quality of results provided to clients by implementing checks to monitor the quality of the laboratory's analytical activities? Examples of such checks include: a.___ Internal quality control procedures (using statistical techniques whenever possible); b.___ Participation in PT or other interlaboratory comparisons; c.___ Using certified reference material and/or in-house quality control using secondary reference materials; d.___ Replicate testing; e.___ Re-testing of retained samples; and/or f.___ Correlation of results for different parameters of a sample (example- TP should be greater than or equal to ortho-P) g.___ Other: _____	😐 🗁				🔔
5.5.3.5.a Does the laboratory implement general procedures to be followed when there are departures from documented policies, procedures, and QC have occurred? - What corrective action procedures are taken when there are QC failures?	☯				♋

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.5.3.5.a Do the procedures to be followed when there is a departure from documented policies, procedures, and QC shall include but are not limited to: a.___ Identify the individuals responsible for assessing each QC data type; b.___ Identify the individuals responsible for initiating and/or recommending corrective actions; c.___ Define how the analyst should treat the data set if the associated QC measurements are unacceptable; d.___ Specify how out-of-control situations and subsequent corrective actions are to be documented; and e.___ Specify procedures for management (including the QA officer) to review corrective action reports. - What general procedures are followed for QC failures?	☯				♋
5.5.3.5.b If a QC measure is out of control and the data is to be reported, are data qualifiers reported with all samples associated with failed QC measures? - How and where are out of control QC controls reported?	😐 ☹ 📂				🔔
5.5.4.b Are all quality control measures assessed and evaluated on an on-going basis, and quality control acceptance limits used to determine the usability of the data?	☺ 😐 📂				🔔
5.5.4.c Does the laboratory have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist?	☯				♋
5.5.4.d Are the quality control protocols specified by the laboratory's method manual followed?	☹ 📂				🔔
5.5.1, 5.5.1.a Does the laboratory establish and maintain a documented quality system appropriate to the type, range and volume of environmental testing activities it undertakes?	☑				
5.6 PERSONNEL					
5.6.1 Does the laboratory maintain records to indicate that it has sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions? - What documentation does the laboratory maintain to ensure that it has sufficient personnel with the necessary requirements?	☯ ☺ 😐 📂				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.6.1 Are personnel responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/technical function?	☺ 😐 ☹ 🗁				🔔
5.6.1 Does each technical staff member have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function?	☺ 😐 ☹ 🗁				🔔
5.6.1 Does each technical staff member have a combination of experience and education to adequately demonstrate a general knowledge of laboratory operations, analytical methods, quality assurance/quality control procedures and records management?	☺ 😐 ☹ 🗁				🔔
5.6.2.a Is there a defined minimum level of qualification, experience, and skills (including basic lab skills such as using a balance, colony counting, aseptic or quantitative techniques) necessary for all positions in the lab? - Who defines the minimum level of qualification for all positions in the laboratory? Where is this documented?	☯				♋
5.6.2.b, C.1 Does the laboratory management maintain records to assure that all technical laboratory staff and/or work cells have demonstrated and documented initial and ongoing proficiency in the activities for which they are responsible? - What records are maintained documenting an analysts/work cells initial and continuing DOC?	😐 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.6.2.c.1-3, 5.6.3 Does laboratory management ensure that training records are kept up-to-date for all technical staff that include: a.___ Evidence that the employee has read, understands, and is using the latest version of the lab's in-house quality documentation; b.___ Training courses or workshops on specific equipment, analytical techniques, or lab procedures; c.___ Training courses in ethical and legal responsibilities including the potential punishments & penalties for violations. d.___ Evidence that the employee has read; acknowledges, and understands their personal & legal responsibilities including potential punishments & penalties for violations; and e.___ Documentation certifying that the employee has read, understands, and agrees to use the latest version of a test method used;					
5.6.2.c.4 Does laboratory management ensure that the training records of each of the technical staff is updated by including documentation of continuing proficiency by at least one of the following once per year by one of the following: a.___ Acceptable performance of a blind sample; b.___ Another demonstration of capability; c.___ Successful analysis of a blind performance sample on a similar test method using the same technology; d.___ Analysis of at least 4 consecutive lab control samples with acceptable levels of precision and accuracy; or e.___ If one of the above cannot be performed, the analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable results. - What technique does the laboratory procedures call for demonstrating continuing capability?					
5.6.2.d Does the laboratory document all analytical and operational activities of the laboratory?					
5.6.2.f Does the laboratory management ensure all sample acceptance criteria (Section 5.11) are verified and that samples are logged into the sample tracking system and properly labeled and stored? - Who has the responsibility of verifying that all sample acceptance criteria are checked and that samples are logged in properly? What is this procedure?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.6.2.g Does the laboratory management document the quality of all data reported by the laboratory?					
5.6.2.h Has the laboratory management developed a proactive program for the detection of improper, unethical, or illegal actions? - Describe the program in place to detect improper, unethical or illegal actions?					
5.7 PHYSICAL FACILITIES					
5.7.1.a Do the laboratory accommodations, test areas, energy sources, lighting, heating and ventilation facilitate proper performance of tests? - What types of safeguards are in place to deal with power surges and brown-outs?					
5.7.1.b, 5.7.2.c Is the environment in which performance of tests take place such that the results are not invalidated or the required accuracy of measurement is not adversely affected?					
5.7.1.b Is particular care taken when such performance of tests are undertaken at sites other than the permanent laboratory premises?					
5.7.1.c Does the laboratory provide for the effective monitoring, control and recording of environmental conditions, as appropriate?					
5.7.1.d In instances where monitoring or control of any of the above mentioned items are specified in a test method or by regulation, does the laboratory meet and document adherence to the laboratory facility requirements?					
5.7.2.a Is there effective separation between neighboring areas when the activities therein are incompatible? (including culture handling or incubation areas and volatile organic chemicals handling areas)					
5.7.2.b Is access to and use of neighboring areas where activities are incompatible defined and controlled?					
5.7.2.c Are adequate measures taken to ensure good housekeeping and to ensure that any contamination does not adversely affect data quality?					

5.7.2.d Are work spaces made available to ensure an unencumbered work area? Work areas include:
a.___ Access and entryways to the laboratory;
b.___ Sample receipt area(s);
c.___ Sample storage area(s);
d.___ Chemical and waste storage area(s); and,
e.___ Data handling and storage area(s).					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.8 EQUIPMENT AND REFERENCE MATERIALS					
5.8.a Does the laboratory furnish all items of equipment (including reference materials) required for the correct performance of tests for which accreditation is sought?					
5.8.a Is equipment outside the permanent control of the laboratory handled so as to ensure the requirements of the NELAC standard are met? - Does the laboratory have any equipment that would be considered outside the permanent control of the laboratory?					
5.8.b Is all equipment properly maintained, inspected and cleaned? - What procedures are in place to ensure that all equipment is maintained, inspected, and cleaned?					
5.8.b Are maintenance procedures documented?					
5.8.c Is any item of the equipment taken out of service, clearly identified if it has been subjected to overloading or mishandling, or gives suspect results, or has been shown by verification or otherwise to be defective? - How is an item of equipment identified if it is out of service?					
5.8.c Does the laboratory, wherever possible, store the equipment at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily?					
5.8.c Does the laboratory examine the effect of a defect in the equipment on previous calibrations or tests?					
5.8.d Is each item of equipment and all reference materials labeled, marked or otherwise identified to indicate its calibration status?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.8.e Do equipment and reference materials records include the following: a.___ The name of the item of equipment b.___ The manufacturer's name, type identification, and serial number or other unique identification c.___ Date received and date placed in service d.___ Current location, where appropriate e.___ If available, condition when received (e.g. new, used, reconditioned) f.___ Copy of the manufacturer's instructions, where available g.___ Dates and results of calibrations and/or verifications and date of the next calibration and/or verification h.___ Details of maintenance carried out to date and planned for the future i.___ History of any damage, malfunction, modification or repair - What records can we look at that show when the last few calibrations occurred?					
5.9 MEASUREMENT TRACEABILITY AND CALIBRATION					
5.9.1 Are all measuring operations and testing equipment having an effect on the accuracy or validity of tests calibrated and/or verified before being put into service and on a continuing basis?					
5.9.1 Does the laboratory have an established program for the calibration and verification of its measuring and test equipment including balances, thermometers and control standards?					
5.9.2.a Are measurements made by the labs traceable to national standards of measurement where available?					
5.9.2.b Does the laboratory maintain a record of all calibration certificates that indicate traceability to national standards of measurement and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification?					
5.9.2.c Does the laboratory provide satisfactory evidence of correlation of results in those cases where traceability to national standards of measurement is not applicable? (For example: participation in a suitable program of inter-laboratory comparisons, proficiency testing, or independent analysis.)					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.9.3.a Are reference standards of measurement (such as Class S or equivalent weights or traceable thermometers) used for calibration only and for no other purpose, unless it is demonstrated that their performance as reference standards has not been invalidated?					
5.9.3.a, 5.9.3.c Are reference standards of measurement calibrated by a body that can provide, where possible, traceability to national or international standard reference materials?					
5.9.3.b Is there a program of calibration and verification for reference standards? - What is the lab's program for calibration & verification of reference standards?					
5.9.3.c Are reference standards and measuring and testing equipment subject to in-service checks between calibrations and verifications, where relevant?					
5.9.4.1.a Is all support equipment maintained in proper working order and records of all activities including service calls kept?					
5.9.4.1.b Is all support equipment calibrated annually, using NIST traceable references when available, over the entire range in which the equipment is used?					
5.9.4.1.b Are the results of support equipment calibration within the specifications required of the application for which it is used? - How are correction factors used if needed?					
5.9.4.1.b Is support equipment that is not within the specifications required of the application: a. ___ Removed from service until it is repaired, or b. ___ Are correction factors to correct all measurements established?					
5.9.4.1.c Are all raw data records retained to document equipment performance?					
5.9.4.1.d Prior to use on each working day, are balances, ovens, refrigerators, freezers, incubators and water baths checked with NIST traceable references (where available) in the expected use range?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.9.4.1.d Is the acceptability for use or continued use of balances, ovens, refrigerators, freezers, incubators and water baths according to the needs of the analysis or application for which it is used? - What is the weight range for the balances? Does that include the tare weight of containers?					
5.9.4.1.e Are mechanical volumetric devices, including burettes, checked for accuracy on at least a quarterly use basis? - Includes: burettes, micropipettors, pipettes, automated pipettes					
5.9.4.1.e Do glass microliter syringes come with a certificate attesting to established accuracy or is the accuracy initially demonstrated and documented by the laboratory?					
5.9.4.1.f Is the temperature, cycle time, and pressure of each autoclave run for chemical tests documented by use of appropriate chemical indicators or temperature recorders and pressure gauges?					
5.10 TEST METHODS AND SOPs					
5.10.1.a Does the laboratory have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests?					
5.10.1.b Are all instructions, standards, manuals and reference data relevant to the work of the laboratory maintained up-to-dated and be readily available to the staff? - How are updated copies of SOPs distributed to the staff who uses them?					
5.10.1.1 Does the laboratory have SOPs that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods?					
5.10.1.1.c, 5.10.1.1.d Are copies of SOPs organized and accessible to all personnel? - How do staff members access necessary SOPs?					
5.10.1.1.e Does each SOP clearly indicate: ___ Effective date of the SOP ___ Revision number ___ Signature(s) of approving authority					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.10.1.2.a, 5.10.1.2.b Does the laboratory have in-house method manual(s) for each accredited analyte or test method that clearly describes the lab's method?					
5.10.1.2.b If test methods are copies of published methods are any changes or selected options in the methods documented and included in the methods manual? - How are changes/modifications to methods noted in the lab's SOPs? Is clear justification provided for the change? Ask at the analyst level.					
5.10.1.2.b Each test method includes or references the following where applicable: a.___ Identification of the test method b.___ Applicable matrix or matrices c.___ Detection limit d.___ Scope and application, including components to be analyzed. e.___ Summary of the test method f.___ Definitions g.___ Interferences h.___ Safety i.___ Equipment and supplies j.___ Reagents and standards; k.___ Sample collection, preservation, shipment and storage; l.___ Quality control; m.___ Calibration and standardization; n.___ Procedure; o.___ Calculations; p.___ Method performance (precision & accuracy data, IDC, etc.); q.___ Pollution prevention; r.___ Data assessment and acceptance criteria for quality control measures; s.___ Corrective actions for out-of-control data; t.___ Contingencies for handling out-of-control or unacceptable data; u.___ Waste management; v.___ References; and w.___ Any tables, diagrams, flowcharts and validation data.					
5.10.2 Does the laboratory use appropriate test methods and procedures for all tests and related activities within its responsibility (including sample collection, handling, transport, storage, preparation, and analysis)?					
5.10.2 Are the test methods and procedures used consistent with the accuracy required and with any standard specifications relevant to the calibrations or test concerned?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.10.2.a Does the laboratory use only the test method specified when the test method is mandated or requested?					
5.10.2.b When specific test methods are not required as in the PBMS approach, does the laboratory use only fully documented and validated test methods (DOC per 5.10.2.1 and Appendix C) that are available to the client and other recipients of relevant reports? - Note: The State of Utah does not accept PBMS methods.					
5.6.3, 5.10.2.1.a, 5.10.2.1.c, Appendix C Is there a record of a satisfactory initial demonstration of method capability performed prior to and institution of any test method? (Not required for a test method that was in use by the lab prior to 7/99 and where there has been no significant changes)					
5.10.2.1.c Does the laboratory have records on file to demonstrate that an initial demonstration of capability is not required for unchanged methods in use prior to 7/99?					
5.10.2.1.e Does the laboratory complete a new demonstration of capability whenever there is a significant change in instrument type, personnel, or test method? - What procedure does the lab use to complete a new DOC when there is a change?					
5.10.2.1.f In a laboratory with specialized work cells, does the group as a unit completes a demonstration of capability?					
5.10.2.1.g When a work cell is employed, and the members of the cell change, does the new employee work with experienced analysts in the area of the work cell where they are employed? - Does the lab use work cells?					
5.10.2.1.g Does the laboratory demonstrate and document acceptable continuing performance checks (e.g. laboratory control samples) each time members in the work cell change?					
5.10.2.1.g Is the initial demonstration of capability repeated with the new work cell if there is a failure in the first 4 sample batch acceptance criteria?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.10.2.1.h Is the performance of the work cell as a group linked to the training records of the individual members of the work cell?					
5.10.3 Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, does the laboratory use documented procedures and appropriate techniques to obtain representative subsamples?					
5.10.4.a Does the laboratory establish SOPs to ensure that the reported data is free from transcription and calculation errors? - How does the lab ensure that reported data is free from errors? What steps are taken?					
5.10.4.b Does the laboratory establish SOPs to ensure that all quality control measures are reviewed, and evaluated before data is reported? - How does the lab ensure that QC measures are reviewed and evaluated before data is reported? Who reviews this data?					
5.10.4.c Does the laboratory establish SOPs addressing manual calculations including manual integrations? - When using manual integrations, are the original chromatograms saved as well as the manually integrated chromatograms?					
5.10.4 Are calculations and data transfers subject to appropriate checks as established in the laboratory's SOPs? - How often are calculations and data transfers checked? Are the calculation cells in spreadsheets protected?					
5.10.5 Do documented procedures exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.10.5.a Does the laboratory retain records for all standards, reagents and media including manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied), date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used unless its reliability is verified by the laboratory? - What is the laboratory's policy for materials received without an expiration date? What resources does the lab have for troubleshooting if a standard or reagent appears to be contaminated?					
5.10.5.b Are original reagent containers labeled with an expiration date?					
5.10.5.c Are detailed records maintained on reagent and standard preparation? - What records are maintained on reagent and standard preparation? What are the processes for re-verifying standards?					
5.10.5.d Do all containers of prepared reagents and standards bear a unique identifier and expiration date and can it be linked to the documentation of its preparation?					
5.10.6.a Does the laboratory ensure that all requirements of Chapter 5 are complied with where computers, automated equipment, or microprocessors are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data?					
5.10.6.b Is computer software tested documented to be adequate for use? (internal audits, personnel training, focus point of QA & QC)					
5.10.6.c Are procedures [ ] **established** and [ ] **implemented** for protecting the integrity of data? - What procedures are established and implemented to protect the integrity of data?					
5.10.6.c Do the procedures include, but not limited to, integrity of data entry or capture, data storage, data transmission and data processing?					

5.11 SAMPLE HANDLING					
5.10.6.d Are computer and automated equipment maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data?					
5.10.6.e Does the laboratory [ ] **establish** appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records and [ ] does the laboratory **implement** those procedures? (ex. Are access codes used?)					
5.11.1.a Does the laboratory have a documented system for uniquely identifying the items to be tested, to ensure that there can be no confusion regarding the identity of such items at any time?					
Relevant Aspect of Standards	**Reference**	**Y**	**N**	**N/A**	**Comments**
5.11.1.a Does the system include identification for all samples, subsamples and subsequent extracts and/or digestates?					
5.11.1.a, 5.11.1.e Does the laboratory assign a unique identification (ID) code to each sample container received in the laboratory? (In cases where the sample collector and analyst are the same individual or the laboratory preassigns numbers to sample containers, the laboratory ID code may be the same as the field ID code.) - How does the lab assign a unique ID to received samples?					
5.11.1.b Does the laboratory sample code maintain an unequivocal link with the unique field ID code assigned each container?					
5.11.1.c Is the laboratory ID code placed on the sample container as a durable label?					
5.11.1.d Is the laboratory ID code entered into the laboratory records and is it the link that associates the sample with related laboratory activities such as sample preparation or calibration?					
5.11.2 Does the laboratory have a written sample acceptance policy that clearly outlines the circumstances under which samples will be accepted or rejected? - Under what circumstances would a sample be rejected?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.11.2 Is data from any sample which does not meet the acceptance policy criteria flagged in an unambiguous manner clearly defining the nature and substance of the variation?	☯ ☹ 🗁				♋
5.11.2 Is the sample acceptance policy made available to sample collecting personnel and does it include at a minimum all the policy?	☹ 🗁				🔔
5.11.2.a to f Does the sample acceptance policy criteria include the following at a minimum? a. ___ Proper, full, and complete documentation, which includes: 1.___ Sample identification, 2.___ Location, 3.___ Date and time of collection, 4.___ Collector's name, 5.___ Preservation type, 6.___ Sample type and 7.___ Any special remarks concerning the sample. b. ___ Proper sample labeling to include: 1.___ Unique identification and 2.___ A labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink. c. ___ Use of appropriate sample containers. d. ___ Adherence to specified holding times. e. ___ Adequate sample volume (Sufficient sample volume must be available to perform the necessary tests). f. ___ Procedures to be used when samples show signs of damage or contamination.	☯ 😐 ☹ 🗁				♋
5.11.3.a Upon receipt, is the condition of the sample recorded, including any abnormalities or departures from standard condition as prescribed in the relevant test method?	☹ 🗁				🔔
5.11.3.a Are all items specified in sample acceptance policy criteria checked?	☹ 🗁				🔔
5.11.3.a.1 Are all samples, which require thermal preservation, considered acceptable if the arrival temperature is either within +/-2°C of the required temperature or in the method specified range? - How is the temp of the samples checked upon receipt? What is the acceptable temp range?	☹ 🗁				🔔
5.11.3.a.1 For samples with a specified temperature of 4°C, are samples considered acceptable with a temperature of just above freezing to 6°C?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.11.3.a.1 In cases where samples are hand delivered to the laboratory immediately after collection and do not meet the temperature criteria considered acceptable, is there evidence that the chilling process has begun such as arrival on ice?					
5.11.3.a.2 Does the laboratory [ ] **have** procedures for checking chemical preservation using readily available techniques, such as pH, free chlorine or temperature, prior to or during sample preparation or analysis and [ ] does the laboratory **implement** those procedures? - Where is this procedure in the SOP?					
5.11.3.b Are the results of all checks recorded?					
5.11.3.c Where there is any doubt as to the item's suitability for testing, where the sample does not conform to the description provided, or where the test required is not fully specified, does the laboratory consult with the client for further instruction before proceeding? - Where there is doubt as to the sample suitability for testing, what steps are taken by lab personnel?					
5.11.3.c Does the laboratory establish whether the sample has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory?					
5.11.3.c If the sample does not meet the sample receipt acceptance criteria does the laboratory do any of the following: a.___ Retain correspondence and/or records of conversations concerning the final disposition of rejected; or b.___ Fully document any decision to proceed with the analysis of samples not meeting acceptance criteria c.___ Is the condition of these samples, at a minimum, noted on the chain of custody or transmittal form and laboratory receipt documents? d.___ Is the analysis data of these samples appropriately "qualified" on the final report?					
5.11.3.d Does the laboratory utilize a permanent, sequential log, such as a logbook or electronic record, to document receipt of all sample containers?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.11.3.d.1 Is the following information recorded in the laboratory chronological log? a.___ Client/Project Name b.___ Date and time of laboratory receipt of sample c.___ Unique laboratory ID code assigned to the sample d.___ Signature or initials of the person making the entries					
5.11.3.d.2 Is the following information unequivocally linked to the log in records, included as a part of the log, or if recorded/documented elsewhere is it a part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample? a.___ Field ID code which identifies each container is linked to laboratory ID code in the sample receipt log. b.___ Date and time of sample collection is linked to the sample container and to the date and time received in the laboratory. c.___Requested analyses (including applicable approved test method numbers) is linked to the laboratory ID code. d.___ Any comments resulting from inspection for sample rejection is linked to the laboratory ID code.					
5.11.3.e Is all documentation, such as memos or transmittal forms that are transmitted to the laboratory by the sample transmitter retained? - Are FedEx, UPS and other carrier labeling and documentation retained?					
5.11.3.f Is a legal chain of custody record, if utilized, maintained?					
5.11.4 Does the laboratory have documented procedures and appropriate facilities to avoid deterioration, contamination or damage to the sample during storage, handling, preparation, and testing?					
5.11.4 Does the laboratory follow any relevant instructions from the client in regards to the storage of a sample?					
5.11.4 Where items have to be stored or conditioned under specific environmental conditions, are those conditions maintained, monitored and recorded? - Where are samples stored if they are required to be under specific conditions?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.11.4.a Are samples stored according to the conditions specified by preservation protocols in the Quality Assurance Manual and/or relative quality documentation?					
5.11.4.a.2 Are samples stored away from all standards, reagents, food and other potentially contaminating sources in such a manner as to prevent cross contamination?					
5.11.4.a.1 Are samples that require thermal preservation stored under refrigeration that is $\pm 2^{o}$ of the specified preservation temperature unless method specific criteria exist? For samples with a specified storage temperature of 4°C, storage at a temperature above the freezing point of water to 6°C shall be acceptable.					
5.11.4.b Are sample fractions, extracts, leachates and other sample preparation fractions stored according to the conditions specified or according to the test method?					
5.11.4.c Where a sample or portion of the sample is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), does the laboratory have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned? - Does the lab have to hold samples secure for reasons or record, safety or value? How is this done?					
5.11.5 Does the laboratory have standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products? - What is the lab's procedure for disposal?					
5.12 RECORDS					
5.12 Does the laboratory maintain a record system to suit its particular circumstances and comply with any applicable regulations?					
5.12 Does the system produce unequivocal, accurate records, which document all laboratory activities?					
5.12 Does the laboratory retain on record all original observations, calculations and derived data, calibration records and a copy of the test report for a minimum of 5 years?					
5.12 Does the laboratory have a written SOP for how the laboratory will carry out legal chain of custody if a client specifies that a sample will be used for evidentiary purposes?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.12.1 Does the record keeping system allow historical reconstruction of all laboratory activities that produced analytical data?					
5.12.1 Is the history of the sample readily understood through the documentation including inter-laboratory transfers of samples and/or extracts?					
5.12.1.a Do the records include the identity of personnel involved in sampling, sample receipt, preparation, calibration or testing?					
5.12.1.b Is all information relating to the laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification documented?					
5.12.1.c Does the record keeping system facilitate the retrieval of all working files and archived records for inspection and verification purposes? (Set format for naming electronic files). - How are records retrieved for inspection and verification if needed? From archives?					
5.12.1.d [ ] Are all changes to records signed or initialed by responsible staff [ ]? And reason for the signature or initials clearly indicated?					
5.12.1.e Are all generated data, except those that are generated by automated data collection systems, recorded directly, promptly and legibly in permanent ink?					
5.12.1.f Are all corrections to record-keeping errors made by one line marked through the error and the individual making the correction signing (or initialing) and dating the correction? - How are corrections to record-keeping errors made?					
5.12.1.f If corrections are made, are entries in records not obliterated by methods such as erasing, overwriting files, or marking up the entries?					
5.12.2.a Are all records, certificates and reports held secure and in confidence to the client?					
5.12.2.a Are NELAP related records available to the accrediting authority?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.12.2.b Are all records necessary for the historical reconstruction of data retained for a minimum of five years from last entry in the records? - How long are records maintained?	☺ 😐 📂				🔔
5.12.2.b Are records which are stored only on electronic media supported by the hardware and software necessary for their retrieval?	☺ 😐 📂				🔔
5.12.2.c Do records that are stored or generated by computers or personal computers have hard copy or write-protected backup copies?	☺ 😐 📂				🔔
5.12.2.d Does the laboratory have a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation storage and reporting? - What is the lab's record management system for notebooks, logbooks, etc?	☺ 😐 📂				🔔
5.12.2.e Is access to archived information documented with an access log? - What safeguards are in place to protect archive records?	☺ 😐 📂				🔔
5.12.2.e Is archived information protected against fire, theft, loss, environmental deterioration, and vermin and, in the case of electronic records, electronic or magnetic sources?	☺ 😐 📂				🔔
5.12.2.f, 4.1.8.e Does the laboratory have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory transfers ownership or goes out of business? - What is the lab's policy regarding the maintenance of records if the lab goes out of business or transfers ownership?	☯ ☺ 😐				♋

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.12.3.1.a-d Does the laboratory retain records of the following procedures to which a sample is subjected while it is in the lab's possession: a.___ Sample preservation including appropriateness of sample container & compliance with holding time requirements b.___ Sample identification, receipt, acceptance or rejection, & log-in c.___ Sample storage & tracking including shipping receipts, sample transmittal forms. d.___ Documented procedures for receipt and retention of test items that includes all provisions necessary to protect the integrity of samples?	☺ 😐 ☹ 📂				🔔
5.12.3.2.a-h Does the laboratory retain : a.___ All original raw data, whether hard copy or electronic, for calibrations, sample analyses, & quality control measures, including analysts work sheets and data output records (chromatograms, strip charts, and other instrument response readout records) - For analysis that have CCC, where can the date of the last calibration be found to link it to the current file? b.___ A written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value; c.___ Copies of final reports d.___ Archived standard operating procedures e.___ Correspondence relating to its activities for a specific project f.___ All corrective action reports, audits, & audit response g.___ Proficiency test results & raw data	☺ 😐 ☹ 📂				🔔
5.12.3.2.a-h Does the laboratory retain : h.___ Records of data review & cross checking procedures					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.12.3.3.a-n Do strip charts, tabular printouts, computer data files, analytical notebooks, and run logs include: a.___ Laboratory sample ID code b.___ Date of analysis and time of analysis if the holding time is 72 hours or less or when time critical steps are included in the analysis (extractions and incubations) c.___ Instrumentation identification and instrument operating conditions/parameters (or reference to such data) d.___ Analysis type (method or technique) e.___ All manual calculations including manual integrations f.___ Analyst's or operator's initials/signature g.____Sample preparation including cleanup & separation protocols, ID codes, volumes, weights, instrument printouts, meter readings, calculations, & reagents used	☺ 😐 ☹ 📂				🔔
5.12.3.3.a-n Do strip charts, tabular printouts, computer data files, analytical notebooks, and run logs include: h.____ Sample analysis i.____ Standard & reagent origin, receipt, preparation, & use j.____ Calibration criteria, frequency, & acceptance criteria - For analysis that has CCC, where can the date of the last calibration be found to link it to the current data? k.____ Data & statistical calculations, review, confirmation, interpretation, assessment, & reporting conventions l.____ Quality control protocols & assessment m.____ Electronic data security, software documentation & verification, software & hardware audits, backups, records of any changes to automated data entries n.___ Method performance criteria including expected quality control requirements	☺ 😐 ☹ 📂				🔔
5.12.3.4 Does the laboratory maintain the following administrative records: a. ___ Personnel qualifications, experience and training records; b. ___ Records of demonstration of capability for each analyst; and c. ___ A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.	😐 ☹ 📂				🔔

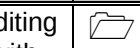
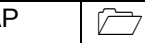
Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.13 REPORTS					
5.13 Does the laboratory report the results of each test, or series of tests carried out by the laboratory in a test report that reports the data accurately, clearly, unambiguously, and objectively? - How are results reported to the client?					
5.13 Does the test report contain all information necessary for the interpretation of the test results and all information required by the method used?					
5.13.a.1 to 10 Unless the laboratory is operated by a facility whose sole function is to provide data for the facility, does the report contain: a.___ A title b.___ Name and address of laboratory d.___ Location where analysis is carried out if different e.___ Phone number and name of contact person f.___ Unique identification of the certificate or report and unique identification of each page, and the total number of pages (This requirement may be presented in several ways: 1.___The total number of pages may be listed on the first page of the report as long as the subsequent pages are identified by the unique report identification and consecutive numbers, or 2.___Each page is identified with the unique report identification, the pages are identified as a number of the total report pages (3 of 10, 1 of 20) 3.___Other methods of identifying the pages in the report may be acceptable as long as it is clear to the reader that discrete pages are associated with a specific report, and that the report contains a specified number of pages.) g.___ Name and address of client, where appropriate and project name if applicable h.___ Description and unambiguous identification of the tested sample including the client identification code					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.13.a.1 to 10 Unless the laboratory is operated by a facility whose sole function is to provide data for the facility, does the report contain: i.___ Identification of results derived from samples that did not meet NELAC acceptance requirements such as improper container, holding time, or temperature. j.___Date of receipt of sample, date and time of sample collection, date(s) of performance test, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 72 hours k.___Identification of the test method used, or unambiguous description of any non-standard method used l.___ If the laboratory collected the sample, reference to sampling procedure m.___ Any deviations from, additions to or exclusions from the test method (such as environmental conditions), and any non-standard conditions that may have affected the quality of the results, and including the use and definitions of data qualifiers					
5.13.a.11 to 17 Does the report contain: a.___ Measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures (such as failed quality control) identified whether data are calculated on dry weight or wet weight, reporting units, and for Whole Effluent Toxicity, identify the statistical package used to provide the data. b.___ When required, a statement of the estimated uncertainty of the test result. c.___ A signature and title, or an equivalent electronic identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue d.___ At the lab's discretion, a statement to the effect that the results relate only to the items tested or to the sample as received by the laboratory e.___ At the lab's discretion, a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory f.___ Clear identification of all test data provided by outside sources, such as subcontracted laboratories, clients, etc.; and g.___ Clear indication of numerical results with values outside of quantitation limits.					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.13.b, 5.13.b.1 Are all applicable elements above readily available for review if not issued in a formal report by an in-house or captive laboratory?					
5.13.b.2 Are all applicable elements above provided to another individual within the organization for preparation of regulatory reports if a formal report is not issued?					
5.13.b.2 Does the facility management ensure that the appropriate report items are in the report to the regulatory authority if the report is prepared by another individual within the organization?					
5.13.c Where the certificate or report contains results of tests performed by sub-contractors, are these results clearly identified by subcontractor name or applicable accreditation number? - How are results from sub-contracted work identified on the report to the client?					
5.13.d After issuance of the report, does the laboratory report remain unchanged?					
5.13.d Are material amendments to a calibration certificate, test report or test certificate after issue made only in the form of a further document, or data transfer including the statement "Supplement to Test Report or Test Certificate, serial number . . . [or as otherwise identified]", or equivalent form of wording?					
5.13.d Do amendments to the formal report meet all the relevant requirements of the Chapter 5 standard?					
5.13.e Does the laboratory notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.13.f Does the laboratory[ ] **have** procedures that ensure, where clients require transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, that the requirements of Chapter 5 are met and that reasonable steps are taken to preserve confidentiality and does the staff [ ] **follow** the documented procedure? - What is the labs procedure for ensuring confidentiality is met regarding transmission of results by telephone, fax, or email?					
5.13.g Does the laboratory certify that the test results meet all requirements of NELAC or provide reasons and/or justification if they do not? - How are methods or analytes flagged on reports if they have dropped off the lab's UT certification or methods or analytes that are not offered in the certification program, if they are to be included in a report with other accredited parameters?					
5.14 SUBCONTRACTING					
5.14.a, 5.14.c Does the laboratory have records to indicate that it advises the client in writing of its intention to sub-contract any portion of the testing to another party?					
5.14.b, 5.14.c Where a laboratory sub-contracts any part of the testing covered under NELAP, does the laboratory have records to document that the work placed with a laboratory is accredited under NELAP or that the laboratory meets applicable statutory and regulatory requirements for the tests to be performed?					
5.14.b Is non-NELAC work performed by a subcontracted laboratory clearly identified in the laboratory report?					
5.15 SERVICES AND SUPPLIES					
5.15.a Does the laboratory use only outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's tests?					
5.15.b Where no independent assurance of the quality of outside support services or supplies is available, does the laboratory have procedures to ensure that purchased equipment, materials and services comply with specified requirements? - What resources does the lab have for troubleshooting if a standard or reagent appears to be compromised? What comparisons are made when new standards are used? What is the process for re-verifying standards?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.15.b Does the laboratory, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned?	☺ 😐 ☹ 🗁				🔔
5.15.c Does the laboratory maintain records of all suppliers from whom it obtains support services or supplies required for tests?	☺ 😐 🗁				🔔
5.16 COMPLAINTS					
5.16 Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of Chapter 5 or otherwise concerning the quality of the laboratory's calibrations or tests, does the laboratory ensure that those areas of activity and responsibility involved are promptly audited? - How is a complaint handled by laboratory staff?	😐 🗁				🔔
5.16 Are records of the complaint and subsequent actions maintained?	🗁				🔔
5.0 INTRODUCTION, PT STUDIES, AND USE OF ACCREDITATION					
5.0 Are all items identified in NELAC Chapter 5 Quality System available for the on-site audit or data audit?	✈ 🗁				
2.5 Do the laboratory's management and all analysts ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis?	☺ 😐 ☹				🔔
6.8.a.1 Does the laboratory post or display their most recent NELAP accreditation certificate or their NELAP-accredited fields of testing in a prominent place in the laboratory facility?	✈				
4.6.1, 6.8.a.2 Does the laboratory make accurate statements concerning their NELAP accreditation fields of testing and NELAP accreditation status? - How are methods or analytes flagged on reports if they have dropped off the lab's UT certification or methods or analytes that are not offered in the certification program, if they are to be included in a report with other accredited parameters?	🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
6.8.a.3 Does the laboratory accompany the accrediting authority's name and/or the NELAC/NELAP logo with at least the phrase "NELAP accredited" and the laboratory's accreditation number or other identifier when the accrediting authority's name is used on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials?					
4.6.1, 6.8.a.4 Does the laboratory use their NELAP certificate, NELAP accreditation status and/or NELAC/NELAP logo in such a manner as to not imply endorsement by the accrediting authority?					

APPENDIX C - Demonstration of Capability Certificate					
Relevant Aspect of Standards	**Reference**	**Y**	**N**	**N/A**	**Comments**
C.1, C.2, 5.6.2.b, 5.10.2.1.d Are initial demonstrations, continuing demonstrations and method certification documented through the use of the forms in the latest approved NELAC document in Appendix C?					
C.1 Does the laboratory use another approach, documented in its Quality Manual, to demonstrate capability for analytes for which spiking is not an option and for which quality control samples are not readily available?					
5.10.2.1.d Does the laboratory retain all associated supporting data necessary to reproduce the analytical results summarized in the IDC certification statement?					
C.1.a Is the QC sample used for the IDC, purchased from an outside source, or if not available, is the QC sample prepared by the laboratory independently from those used in instrument calibration?					
C.1.b Is the concentrate of the QC sample diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified, or if not specified, to a concentration approximately 10 times the method-stated or laboratory-calculated method detection limit?					
C.1.c Are four aliquots prepared and analyzed according to the method either concurrently or over a period of days?					
C.1.d Is the mean recovery and standard deviation for each parameter of interest calculated in the units used for reporting (such as mg/L)?					
C.1.d When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, does the laboratory assess performance against established and documented criteria?					
C.1.e Is the information from **C.10.d** above compared to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria)?					
C.1.e Does the lab wait to begin the analysis of actual samples until all parameters of interest meet acceptance criteria?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
C.1.f If one or more of the test parameters do not meet the acceptance criteria, is the problem corrected followed by [ ] repeated analysis of the four aliquots for all parameters or [ ] at least for those that failed to meet criteria?					
C.2 Is a copy of the initial demonstration of Capability Certificate (IDC) in the personnel records for each employee performing a test method?					

APPENDIX D.1 - Chemical Testing Detailed Method Review					
The findings and observations recorded here are based upon the evaluation of the following records:					
Relevant Aspect of Standards	**Reference**	**Y**	**N**	**N/A**	**Comments**
5.1.b, 5.9.4.2 Does the laboratory demonstrate that it meets all requirements contained in a mandated test method or by regulation, even if the requirement is more stringent than the corresponding NELAC standard? (If it is unclear which requirements are more stringent, the standard from the method of regulation shall be followed)	☹ 🗁				🔔
D.1 Are the quality control protocols specified by the laboratory's method manual followed by all analysts?	☹ 🗁				🔔
D.1 Are all essential quality control measures in Appendix D incorporated in the lab's method manual?	☹ 🗁				🔔
D.1 Are all quality control measures assessed and evaluated on an on-going basis?	☹ 🗁				🔔
D.1.1.a Does the laboratory have procedures for developing acceptance/rejection criteria where no method or regulatory criteria exists?	☹ 🗁				🔔
D.1.1.a Is the method blank processed along with and under the same conditions as the associated samples include all steps of the analytical procedure? - What statistical analysis is used by the lab to develop QC ranges?	☹ 🗁				🔔
D.1.1.a Are any affected samples associated with a contaminated method blank reprocessed for analysis or are the results reported with appropriate data qualifying codes?	☹ 🗁				🔔
D.1.1.a Is a method blank performed 1 per preparation batch, per matrix type?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.1.1.a In those instances for which there is no separate preparation method is the batch defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples?	☹ 🗁				🔔
D.1.1.a Does the method blank consist of a matrix that is similar to the associated samples and is known to be free of the analytes of interest?	☹ 🗁				🔔
D.1.1.a Is each method blank critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch?	☹ 🗁				🔔
D.1.1.a, D.1.1.a.1, D.1.1.a.2 Is the source of contamination investigated and measures taken to minimize or eliminate the problem and affected samples reprocessed or Is data appropriately qualified if: 1. The concentration of a targeted analyte in the blank is at or above the reporting limit as established by the test method or by regulation, AND is greater than 1/10 of the amount measured in any sample. **2.** The blank contamination affects the sample results as per the test method requirements or the individual project data quality objectives.	☹ 🗁				🔔
A LCS (sample matrix free of analytes of interest, spiked with a verified known amount of analyte) or a media containing known and verified concentrations of analytes or as Certified Reference Material is called a _____ by the laboratory.					
D.1.1.b.1 Is a LCS performed at a frequency of 1 per preparation batch of per matrix type, except for analytes for which spiking solutions are not available?	☹ 🗁				🔔
D.1.1.b.1 In those instances for which no separate preparation method is used (example: volatiles in water) is the batch defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples? - A prep batch must not exceed a 24-hour period.	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.1.1.b.1 If the matrix spike is used as the LCS, is the acceptance criteria as stringent as the LCS?	☹ 🗁				🔔
D.1.1.b.1 Are the components spiked those that are specified by the mandated test method or other regulatory requirement or as requested by the client, except for those circumstances in **D.1.1.b.1** below?	☹ 🗁				🔔
D.1.1.b.1 In the absence of specified spiking components does the laboratory spike per the following: a. ___ For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, is the spike chosen so that it represents the chemistries and elution patterns of the components to be reported? b.___ For those test methods that have extremely long lists of analytes, is a representative number chosen as below? 1.___ Are the analytes selected that representative of all analytes reported? 2___ Is the following criteria used for determining the minimum number of analytes to be spiked. a) ___ Does the laboratory insure that all targeted components are included in the spike mixture over a 2 year period.? b)___ For methods that include 1-10 targets, are all components spiked?; c)___ For methods that include 11-20 targets, are at least 10 or 80% spiked, whichever is greater; d)___ For methods with more than 20 targets, are at least 16 components spiked?	☹ 🗁				🔔
D.1.1.b.1 Are the results of the individual batch LCS calculated in percent recovery?	☹🗁				🔔
D.1.1.b.1 Does the laboratory document the calculation for percent recovery?	☹🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.1.1.b.1 Is the individual LCS compared to the acceptance criteria as published in the mandated test method or where there are no established criteria,does the laboratory determine internal criteria and document the method used to establish the limits or utilize client specified assessment criteria?	☹ 🗁				🔔
D.1.1.b.1 Are samples analyzed along with a LCS determined to be "out of control" considered suspect and the samples reprocessed and re-analyzed or is the data reported with appropriate data qualifying codes?	☹ 🗁				🔔
Sample prepared by adding a known mass of target analyte to a specific amount of matrix sample are called _____ by the laboratory					
D.1.1.c Does the laboratory document procedures for determining the effect of the sample matrix on method performance?	☹ 🗁				🔔
D.1.1.c Does the laboratory have procedures in place for tracking, managing, and handling matrix specific QC criteria including spiking appropriate components at appropriate concentrations, calculating recoveries and relative percent difference, evaluating and reporting results based on performance of the QC samples?-	☹ 🗁				🔔
D.1.1.c Is the frequency of the analysis of matrix specific samples determined as part of a systematic planning process (e.g. Data Quality Objectives) or as specified by the required mandated test method?	☹ 🗁				🔔
D.1.1.c Are the components spiked those specified by the mandated test method, where applicable?	☹ 🗁				🔔
D.1.1.c Are any permit specified analytes, as specified by regulation or client requested analytes also included?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.1.1.c, D.1.1.c.a, D.1.1.c.b, D.1.1.c.c If there are no specified components, does the laboratory spike per the following: a.___ For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, is the spike chosen whicht represents the chemistries and elution patterns of the components to be reported? b.___ For those test methods that have extremely long lists of analytes, are all analytes used, or are a representative number chosen using the following criteria: 1. For methods that include 1-10 targets, spike all components; 2.For methods that include 11-20 targets, spike at least 10 or 80%, whichever is greater; 3. For methods with more than 20 targets, spike at least 16 components.	☹ 📂				🔔
D.1.1.c Does, the laboratory include all targeted components in the spike mixture over a 2 year period?	☹📂				🔔
D.1.1.c Is the matrix spike used to assess the precision and accuracy of analytical results in a given matrix and are they expressed as percent recovery (%R) and relative percent difference (RPD)?	☹ 📂				🔔
D.1.1.c Does the laboratory document the calculation for relative percent difference?	☹ 📂				🔔
D.1.1.c Are the results compared to the acceptance criteria in the mandated test method when published?	☹ 📂				🔔
D.1.1.c Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits?	☹ 📂				🔔
D.1.1.c For matrix spike results outside established criteria, is corrective action documented or is the data reported with appropriate data qualifying codes?	☹ 📂				🔔
Replicate aliquots of the same sample taken through the entire analytical procedure are known as _____ by the laboratory.					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.1.1.d Is the frequency of the analysis of matrix duplicates determined as part of a systematic planning process (e.g. Data Quality Objectives) or as specified by the mandated test method?	☹ 🗁				🔔
D.1.1.d Are matrix duplicates performed on replicate aliquots of actual sample?	☹🗁				🔔
D.1.1.d Are the results from matrix duplicates primarily designed to assess the precision of analytical results in a given matrix and are they expressed as relative percent difference (RPD) or another statistical treatment (e.g., absolute differences)?	☹ 🗁				🔔
D.1.1.d Does the laboratory document the calculation for relative percent difference or other statistical treatments?	☹ 🗁				🔔
D.1.1.d Are the results compared to the method acceptance criteria when published in the mandated test method?	☹ 🗁				🔔
D.1.1.d Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits?	☹ 🗁				🔔
D.1.1.d For matrix duplicates results outside established criteria, is corrective action documented or is the data reported with appropriate data qualifying codes?	☹ 🗁				🔔
D.1.1.e Are surrogate compounds added to all samples, standards, and blanks, whenever possible, for all organic chromatography methods?	☹ 🗁				🔔
D.1.1.e Are the results of surrogate recoveries compared to the acceptance criteria published in the mandated test method?	☹ 🗁				🔔
D.1.1.e Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits?	☹ 🗁				🔔
D.1.1.e Are surrogates outside the acceptance criteria evaluated for the effect indicated for the individual sample results?	☹ 🗁				🔔
D.1.1.e Is the appropriate corrective action guided by the data quality objectives or other site specific requirements?	☹ 🗁				🔔
D.1.1.e Are results reported from analyses with surrogate recoveries outside the acceptance criteria with appropriate data qualifiers?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.1.2 Does the laboratory utilize test methods that provide detection limits that are appropriate and relevant for the intended use of the data?	☹ 🗁				🔔
D.1.2 Does the laboratory use detection limits that are determined by the protocol in the mandated test method or applicable regulation?	☹ 🗁				🔔
D.1.2 If the protocol for determining detection limits is not specified, does the selection made by the laboratory reflect instrument limitations and the intended application of the test method?	☹ 🗁				🔔
D.1.2.b Are detection limits initially determined [ ] in a matrix free of target analytes or interferences or in the matrix of interest or [ ] determined in the matrix of interest?	☹ 🗁				🔔
D.1.2.c Are detection limits determined each time there is a change that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis?	☹ 🗁				🔔
D.1.2.d Are all sample processing steps of the analytical method included in the determination of the detection limit?	☹ 🗁				🔔
D.1.2.e Are all procedures used to determine detection limits documented, including the matrix type and is all supporting data retained?	☹ 🗁				🔔
D.1.2.f Does the laboratory have established procedures to relate detection limits with quantitation limits?	☹ 🗁				🔔
D.1.2.g Are the test method's quantitation limits established and above the detection limit?	☹ 🗁				🔔
D.1.3 Are procedures for data reduction, such as use of linear regression, documented?	☹ 🗁				🔔
5.9.4.2, 5.9.4.2.1.c Is only the initial instrument calibration used directly for quantitation?	☹ 🗁				🔔
5.9.4.2.1.a Do the SOPs or the test method SOP reference include the details of the initial calibration procedures, including calculations integrations, and acceptance criteria associated statistics?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.9.4.2.1.a When initial instrument calibration procedures are referenced in the test method, are the referenced material retained by the laboratory and be available for review?	☹ 🗁				🔔
5.9.4.2.1.b, 5.9.4.2.2.c Are sufficient raw data records retained to permit reconstruction of the initial and continuing calibrations using as appropriate, but not limited to: a.___ Calibration date b.___ Test method c.___ Instrument d.___ Analysis date e.___ Each analyte name f.___ Analyst's initials or signature g.___ Concentration and response h.___ Response i.___ Calibration curve or response factor, or j.___ Unique equation or coefficient used to reduce instrument responses to concentration.	☹ 🗁				🔔
5.9.4.2.1.d Are all initial calibrations verified with a standard obtained from a second source or lot that is traceable to a national standaed when available? (if the lot can be demonstrated from the manufactureras prepared independently from other lots)	☹ 🗁				🔔
5.9.4.2.1.e Is the criteria for the acceptance of an initial calibration established (corr. coefficient or relative percent difference)?	☹ 🗁				🔔
5.9.4.2.1.f If the results of samples are not bracketed by the initial calibration, are the results reported as having less certainty (defined qualifiers, flags, or explanation in the case narrative)?	☹ 🗁				🔔
5.9.4.2.1.f Is the lowest calibration standard of the initial calibration above the detection limit?	☹ 🗁				🔔
5.9.4.2.1.g Are corrective actions performed if the results of the initial calibration are outside of established acceptance criteria?	☹ 🗁				🔔
5.9.4.2.1.g Is data associated with unacceptable initial instrument calibration not reported?	☹ 🗁				🔔
5.9.4.2.1.h The initial calibration standards include concentrations that are at or below the regulatory limit/decision level, if these limits are known unless these are below the laboratory's demonstrated detection limit?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.9.4.2.1.i If a reference or mandated method does not specify the number of calibration standards, is the minimum number used 2, not including a blank or zero standard?	☹ 🗁				🔔
5.9.4.2.1.i Does the laboratory have an SOP for determining the number of points for establishing the initial calibration?	☹ 🗁				🔔
5.9.4.2, 5.9.4.2.2 Is a continuing instrument calibration verification used to confirm the continued validity of the initial calibration with each sample batch?	☹ 🗁				🔔
5.9.4.2.2.a Are the details of the continuing instrument calibration procedure, calculations, and associated statistics included or referenced in the test method SOP?	☹ 🗁				🔔
5.9.4.2.2.b Is a continuing instrument calibration verification repeated at the beginning and end of each analytical batch? (If an internal standard is used, only one continuing calibration verification must be analyzed per analytical batch)	☹ 🗁				🔔
5.9.4.2.2.b Are the concentrations of the continuing calibration standards at the beginning and the end varied within the established calibration range?	☹ 🗁				🔔
5.9.4.2.2.c Do the continuing calibration verification records explicitly connect the continuing verification data to the initial instrument calibration?	☹ 🗁				🔔
5.9.4.2.2.d Does the laboratory have established acceptance criteria (relative percent difference) of a continuing calibration verification analysis?	☹ 🗁				🔔
5.9.4.2.2.e Are corrective actions performed if the results of the continuing calibration verifications are outside of established acceptance criteria?	☹ 🗁				🔔
5.9.4.2.2.e If routine corrective action fails to produce a second consecutive (immediate) calibration verification within acceptance criteria, does the lab either perform a new initial calibration or analyze 2 consecutive acceptable calibration verifications before analyzing new samples?	☹ 🗁				🔔
5.9.4.2.2.e If sample data associated with a failed calibration verification is reported, does the laboratory qualify the data?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.9.4.2.2.e.i If there was a high bias and there is a failed continuing calibration verification, is only data associated with samples that are only non-detects reported as qualified data? (Other affected samples are reanalyzed after a new curve has been established, evaluated and accepted)	☹ 🗁				🔔
5.9.4.2.2.e.ii If there was a low bias and there is a failed continuing calibration verification, is only data associated with samples that have a result greater than the maximum regulatory limit/decision level reported as qualified data? (Other affected samples are reanalyzed after a new curve has been established, evaluated and accepted)	☹ 🗁				🔔
D.1.4.a, 5.9.2.a-c Is the source of standards traceable to national standards or proven through inter-laboratory studies?	☹ 🗁				🔔
D.1.4.b.1 In methods where the purity of reagents is not specified, is analytical reagent grade used?	☹ 🗁				🔔
D.1.4.b.1 Does the laboratory use reagents of the purity or of greater purity than that specified in the method?	☹ 🗁				🔔
D.1.4.b.1 Is the container label checked and documented to verify that the purity of the reagents meets the requirements of the particular method?	☹ 🗁				🔔
D.1.4.b.2 Is the quality of water sources monitored and documented to meet method specified requirements?	☹ 🗁				🔔
D.1.4.b.3 Does the laboratory verify the concentration of titrants in accordance with written laboratory procedures? - How are titrants verified?	☹ 🗁				🔔
D.1.5.a Does the laboratory develop and document acceptance criteria for retention time windows?	☹ 🗁				🔔
D.1.5.b Is confirmation performed for organic tests such as pesticides, herbicides, or acid extractable or when recommended by the analytical method to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory? Note: Confirmation is not required when the analysis involves the use of a mass spectrometer.	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.1.5.b If confirmation not performed, is it based on client written stipulation?	☹ 🗁				🔔
D.1.5.b Does the laboratory document all confirmations?	☹ 🗁				🔔
D.1.5.c Does the laboratory document acceptance criteria for mass spectral tuning?	☹ 🗁				🔔
D.1.6.a Does the laboratory assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used?	☹ 🗁				🔔
D.1.6.b Is glassware cleaned to meet the sensitivity of method?	☹ 🗁				🔔
D.1.6.b Are all cleaning and storage procedures that are not specified by the method documented in laboratory records and SOPs?	☹ 🗁				🔔

APPENDIX D.2 - Whole Effluent Testing Detailed Method Review					
The findings and observations recorded here are based upon the evaluation of the following records:					
Relevant Aspect of Standards	**Reference**	**Y**	**N**	**N/A**	**Comments**
5.1.b, 5.9.4.2 Does the laboratory demonstrate that it meets all requirements contained in a mandated test method or by regulation, even if the requirement is more stringent than the corresponding NELAC standard? (If it is unclear which requirements are more stringent, the standard from the method of regulation shall be followed)	☹ 🗁				🔔
D.2 Are the quality control protocols specified by the laboratory's method manual followed by all analysts?	☹ 🗁				🔔
D.2 Are all essential quality control measures in Appendix D incorporated in the lab's method manual?	☹ 🗁				🔔
D.2 Are all quality control measures assessed and evaluated on an on-going basis?	☹ 🗁				🔔
D.2 Does the laboratory have procedures for developing acceptance/rejection criteria where no method or regulatory criteria exists?	☹ 🗁				🔔
D.2.1.a.1 Does the laboratory demonstrate its ability to obtain consistent results with reference toxicants before it performs toxicity tests with effluents or other environmental samples for regulatory compliance purposes?	☹ 🗁				🔔
D.2.1.a.1.i Does the laboratory determine intra-laboratory precision by performing five or more acceptable reference toxicant tests for each test method and species with different batches of organisms and appropriate negative controls (water, sediment, or soil)?	☹ 🗁				🔔
D.2.1.a.1.ii Does the laboratory maintain control charts for the control performance and reference toxicant statistical endpoint (such as NOEC or ECp)?	☹ 🗁				🔔
D.2.1.a.1.ii Does the laboratory evaluate the intra-laboratory variability with a specific reference toxicant for each method?	☹ 🗁				🔔
D.2.1.a.2 Is ongoing laboratory performance demonstrated by performing regular reference toxicant tests for each test method and species in accordance with the minimum frequency requirements specified in **D.2-19** to **D.2-23**?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.2.1.a.2.i Are intra-laboratory precision on an ongoing basis determined through the use of reference toxicant tests and plotted in quality control charts?	☹ 🗁				🔔
D.2.1.a.2.i Are the control charts plotted as point estimate values, such as EC25 for chronic tests and LC50 for acute tests, or as appropriate hypothesis test values, such as the NOEC or NOAEC, over time within a laboratory?	☹ 🗁				🔔
D.2.1.a.2.ii For endpoints that are point estimates (ICp, ECp) are control charts constructed by plotting the cumulative mean and the control limits which consist of the upper and lower 95% confidence limits (+ 2 std. dev.) with these values re-calculated with each successive test result?	☹ 🗁				🔔
D.2.1.a.2.ii For endpoints from hypothesis tests (NOEC, NOAEC) are the values plotted directly and the control limits consist of one concentration interval above and below the concentration representing central tendency (i.e. the mode)?	☹ 🗁				🔔
D.2.1.a.2.iii After 20 data points are collected for a test method and species, is the control chart maintained using only the 20 most recent data points? (Each successive mean value and control limit is calculated using only the last 20 values) - This is often part of the report to clients.	☹ 🗁				🔔
D.2.1.a.2.iv [ ] Are test results which fall outside of control chart limits at a frequency of 5% or less, or which fall just outside control chart limits (especially in the case of highly proficient laboratories which may develop relatively narrow acceptance limits over time), not rejected *de facto* [ ] Are such data evaluated in comparison with control chart characteristics including the width of the acceptance limits and the degree of departure of the value from acceptance limits	☹ 🗁				🔔
D.21.a.2.v Is an acceptance/rejection policy for reference toxicant data developed which considers test dilution factor, test sensitivity (for hypothesis test values), testing frequency, out-of-control test frequency, relative width of acceptance limits and degree of difference between test results and acceptance limits?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.2.1.a.2.vi [ ] In the case of reference toxicant data which fails to meet acceptance criteria, are the results of environmental toxicity tests conducted during the affected period suspect and regarded as provisional? [ ] In this case is the test procedure examined for defects and the test repeated if necessary, using a different batch of organisms, as soon as possible or the data is qualified?	☹ 🗁				🔔
D.2.1.a.3 Is the frequency of reference toxicant testing compliant with the EPA or state permitting authority requirements? - EPA is monthly.	☹ 🗁				🔔
D.2.1.a.3.i Is each batch of test organisms obtained from an outside source, field collection or from laboratory spawning of field-collected species not amenable to routine laboratory culture (for example, sea urchins and bivalve mollusks) evaluated with a reference toxicant test of the same type as the environmental toxicity test within the seven days preceding the test or concurrently with the test?	☹ 🗁				🔔
D.2.1.a.3.ii Are test organisms obtained from in-house laboratory cultures tested with reference toxicant tests at least once each month for each test method?	☹ 🗁				🔔
D.2.1.a.3.ii If a given species produced by in-house cultures is used only monthly, or less frequently, is a reference toxicant test of the same type performed with each environmental toxicity test?	☹ 🗁				🔔
D.2.1.a.3.iii For test methods and species commonly used in the laboratory, but which are tested on a seasonal basis (e.g. sea urchin fertilization tests), are reference toxicant tests conducted for each month the method is in use?	☹ 🗁				🔔
D.2.1.a.4 If the state or permitting authority identifies a reference toxicant or dilution series for a particular test, does the laboratory follows the specified requirements? - UT does not have requirements.	☹ 🗁				🔔
D.2.1.a.4 Do all reference toxicant tests conducted for a given test method and species use the same reference toxicant, test concentrations, dilution water and data analysis methods?	☹ 🗁				🔔
D.2.1.a.4 A dilution factor of 0.5x or greater is used for both acute and chronic tests?	☹🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.2.1.a.5 Are reference toxicant tests conducted following the same procedures as the environmental toxicity tests for which the precision is being evaluated unless otherwise specified in the test method (for example, 10-day sediment tests employ 96-h water-only reference toxicant tests)?	☹ 🗁				🔔
D.2.1.a.5 Is the test duration, dilution or control water, feeding, organism age, age range and density, test volumes, renewal frequency, water quality measurements, and the number of test concentrations, replicates and organisms per replicate the same as specified for the environmental toxicity test?	☹ 🗁				🔔
D.2.1.b.1 Is the use, type, and frequency of testing of negative controls as specified by the test method followed?	☹ 🗁				🔔
D.2.1.b.2 Are additional negative controls included when there are sample adjustments made (ex. Addition of sodium hydroxide for pH or thiosulfate for dechlorination) or solvent carriers are used in the test?	☹ 🗁				🔔
D.2.1.b.3 Is the test acceptability criteria as specified in the test method achieved for both the reference toxicant and effluent or environmental sample toxicity test?	☹ 🗁				🔔
D.2.1.b.3 Is the test acceptability criteria calculated and does it meet the method requirements for performing toxicity tests?	☹ 🗁				🔔
D.2.4.a If the Dunnett's procedure used to calculate the statistical minimum significant difference (SMSD), is the SMSD calculated using the formula specified by the method?	☹ 🗁				🔔
D.2.4.a Is the SMSD reported with the test results?	☹ 🗁				🔔
D.2.4.b Does the laboratory estimate the minimum significant difference for non-normal distribution and/or heterogeneous variances? - Probably in the software program.	☹ 🗁				🔔
D.2.4.c Are the confidence intervals reported as a measure of the precision around the point estimate value (LCp, ICp, or ECp)?	☹ 🗁				🔔
D.2.4.d Is the SMSD calculated and reported for only hypothesis test values, such as the NOEC or NOAEC?	☹ 🗁				🔔
D.2.5.a If required, are the methods of data analysis and endpoints specified by language in the permit or the test method?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.2.5.b Is the data plotted in the form of a curve relating to the dose of chemical or concentration of sample to cumulative percentage of test organisms demonstrating a response such as death?					
D.2.6.a Is the grade of all reagents used in the toxicity tests as specified in the method?					
D.2.6.a Are all reference standards prepared from analytical reagent grade or better chemicals?					
D.2.6.a Is the preparation of all standards and reference toxicants documented? - Where are they documented? Are the containers labeled with an expiration date?					
D.2.6.b, 5.10.5.a Does the laboratory retain records for all standards and reagents associated with chemical measurements, such as dissolved oxygen, pH or specific conductance as required by **5.10-26** through **5.10-31**?					
D.2.6.c Only reagent-grade water collected from distillation or deionization units (> 17 megohm resistivity) is used to prepare reagents?					
D.2.8.a If closed refrigerator-sized incubators are used, are culturing and testing of organisms separated to avoid loss of cultures due to cross-contamination?					
D.2.8.b Is laboratory space adequate for the types and numbers of tests performed?					
D.2.8.b Does the building provide adequate cooling, heating and illumination for conducting testing and culturing?					
D.2.8.b Is hot and cold running water available for cleaning equipment?					
D.2.8.c Is air used for aeration of test solutions, dilution waters and cultures free of oil and fumes?					
D.2.8.d Does the laboratory or a contracted outside expert positively identify test organisms to species on an annual basis?					
D.2.8.d Are the taxonomic reference (citation and page(s)) and the names(s) of the taxonomic expert(s) on file at the laboratory?					
D.2.8.d When organisms are obtained from an outside source does the supplier provide the taxonomic reference (citation and page(s)) and the names(s) of the taxonomic expert(s) and are these kept on file at the laboratory?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.2.8.e Are instruments used for routine measurements of chemical and physical parameters such as pH, DO, conductivity, salinity, alkalinity, hardness, chlorine, and weight calibrated, and/or standardized per manufacturer's instructions and standard.1-57 through D.1-69?	☹ 🗁				🔔
D.2.8.e Is temperature calibrated per section 5.9.4.2.1?	☹ 🗁				🔔
D.2.8.e Are all chemical and physical measurements and calibrations documented?	☹ 🗁				🔔
D.2.8.f Does the laboratory maintain the test temperature as specified in the methods manual?	☹ 🗁				🔔
D.2.8.f Is the temperature control equipment adequate to maintain the required test temperature(s)?	☹ 🗁				🔔
D.2.8.f Is the average daily temperature of the test solutions maintained within $1^{o}C$ of the selected test temperature, for the duration of the test?	☹ 🗁				🔔
D.2.8.f Is the test temperature measured at least once per 24-hour period for the duration of the test?	☹ 🗁				🔔
D.2.8.f Is the test temperature for continuous flow toxicity tests recorded and monitored continuously?	☹ 🗁				🔔
D.2.8.g Does reagent grade water, prepared by any combination of distillation, reverse osmosis, ion exchange, activated carbon and particle filtration, meet the following requirements as verified by monthly measurement: a.___ Conductivity less than or equal to 0.1 umhos or resistivity greater than or equal to 17 megohm, b.___ pH 5.5 to 7.5 S.U. and c.___ Total residual chlorine non-detectable.	☹ 🗁				🔔
D.2.8.h Is the quality of the standard dilution water used for testing or culturing sufficient to allow satisfactory survival, growth and reproduction of the test species as demonstrated by routine reference toxicant tests and negative control performance?	☹ 🗁				🔔
D.2.8.h Is water used for culturing and testing analyzed for toxic metals and organics whenever the minimum acceptability criteria for control survival, growth or reproduction are not met and no other cause, such as contaminated glassware or poor stock, can be identified?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.2.8.h For those analytes not listed, or for which the measured concentration or detection limit is greater than the method-specified limit, does the laboratory demonstrate that the analyte at the measured concentration or reported detection limit does not exceed one tenth the expected chronic value for the most sensitive species tested and/or cultured?					
D.2.8.h Is the expected chronic value based on professional judgement and the best available scientific data? (The "USEPA Ambient Water Quality Criteria Documents" and the EPA AQUIRE database provide guidance and data on acceptability and toxicity of individual metals and organic compounds).					
D.2.8.i For each new batch of food used for culturing and testing, is the performance of organisms fed with the new food compared with the performance of organisms with a food of known quality?					
D.2.8.i If the food is used for culturing, is its suitability determined using a a measure that evaluates the effect of food quality on survival and growth or reproduction of each of the relevant test species?					
D.2.8.i Where applicable, are foods used only in chronic toxicity tests evaluated using the reference toxicant regularly employed in the laboratory QA program and compared with results of previous test(s) using a food of known quality?					
D.2.8.i In the case of algae, rotifers or other cultured foods, which are collected as a continuous batch, is the quality assessed, using side-by-side tests as described above, each time new nutrient stocks are prepared, a new starter culture is employed or when a significant change in culture conditions occurs?					
D.2.8.i Does the laboratory have written procedures for the statistical evaluation of food acceptance?					
D.2.8.j Is food used to culture organisms used in bioaccumulation tests analyzed for the compounds to be measured in the bioaccumulation tests?					
D.2.8.k Is the test chamber size and test solution volume as specified in the methods manuals?					
D.2.8.k Are all test chambers used in a test the same size?					
D.2.8.l Are test organisms fed the quantity and type food or nutrients specified in the test method?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.2.8.l Are test organisms also fed at the intervals specified in the test methods?	☹ 🗁				🔔
D.2.8.m Are all organisms in a test from the same source? Where available, are certified seeds used for soil tests?	☹ 🗁				🔔
D.2.8.n Do all organisms used in tests, or used as broodstock to produce neonate test organisms (for example cladocerans and larval fish), appear healthy, show no signs of stress or disease and exhibit acceptable survival (90% or greater) during the 24 hour period immediately preceding use in tests? - Watch for stress and brood size.	☹ 🗁				🔔
D.2.8.o Are all materials used for test chambers, culture tanks, tubing, etc. and coming in contact with test samples, solutions, control water, sediment or soil or food non-toxic and cleaned as described in the test methods? (Materials must not reduce or add to sample toxicity. Appropriate materials for use in toxicity testing and culturing are described in the referenced manuals).	☹ 🗁				🔔
D.2.8.p Is the light intensity and photoperiod maintained as specified in the methods manuals?	☹ 🗁				🔔
D.2.8.p Are light intensity measurements made and recorded on a yearly basis and the photoperiod documented at least quarterly? - Measured in 50-100ft Candle units.	☹ 🗁				🔔
D.2.8.p Is the light intensity measured and recorded at the start of each algal and plant test?	☹ 🗁				🔔
D.2.8.q At a minimum, during aquatic chronic testing are the DO and pH measured daily in at least one replicate of each concentration?	☹ 🗁				🔔
D.2.8.q In static-renewal tests is DO measured at both the beginning and end of each 24-h exposure period? (May be measured in old and new solutions prior to organism transfer, or after organism transfer)	☹ 🗁				🔔
D.2.8.q Is pH measured at the end of each exposure period (i.e. in old solutions)?	☹ 🗁				🔔
D.2.8.r Is the health and culturing conditions of all organisms used for testing documented by the testing laboratory?	☹ 🗁				🔔
D.2.8.r Does that documentation include culture conditions (e.g. salinity, hardness, temperature, pH) and observations of any stress, disease or mortality?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.2.8.r If test organisms are obtained from an outside source, is documentation of these water quality parameters and biological observations for each lot of organism received?	☹ 🗁				🔔
D.2.8.r Does the laboratory also record each of these observations and water quality parameters upon the arrival of the organisms at the testing laboratory?	☹ 🗁				🔔
D.2.8.s Are the age and the age range of the test organisms specified in the method manuals?	☹🗁				🔔
D.2.8.s Is supporting information, such as hatch dates and times, times of brood releases and metrics (for example, chironomid head capsule width) documented?	☹ 🗁				🔔
D.2.8.t Is the maximum holding time of effluents (lapsed time from sample collection to first use in a test) 36 hours and the last use of the sample in test renewals does exceed 72 hours unless permission of the permitting authority has been received?	☹ 🗁				🔔
D.2.8.u Are all samples chilled to 4°C during or immediately after collection and maintained at just above freezing to 6°C?	☹ 🗁				🔔
D.2.8.v Are organisms obtained from an outside source from the same batch? - EPA requires 3 replicates.	☹🗁				🔔
D.2.8.v Do chronic tests have a minimum of four replicates per treatment?	☹ 🗁				🔔
D.2.8.w Does the control population of Ceriodaphnia in chronic effluent or receiving water tests contain no more than 20% males? - Ideally there would be no males.	☹ 🗁				🔔
D.2.8.x Are dissolved oxygen and pH in aquatic tests within acceptable range at test initiation?	☹ 🗁				🔔
D.2.8.x Is aeration (minimal) provided to tests if, and only if, acceptable dissolved oxygen concentrations cannot be otherwise maintained or if specified by the test method?	☹ 🗁				🔔
D.2.8.y Are the test soils or sediments within the geochemical tolerance range of the test organism?	☹ 🗁				🔔
D.2.8.z When the test is conditionally accepted because temperature, dissolved oxygen, pH and other specified conditions fall outside specifications is the acceptability of the test dependent on the degree of the departure and the objectives of the tests?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.2.8.z Is the acceptability of the test dependent on the experience and professional judgment of the technical employee and the permitting authority?	☹				

APPENDIX D.3 - Microbiology Testing Detailed Method Review

The findings and observations recorded here are based upon the evaluation of the following records:

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
5.1.b, 5.9.4.2 Does the laboratory demonstrate that it meets all requirements contained in a mandated test method or by regulation, even if the requirement is more stringent than the corresponding NELAC standard? (If it is unclear which requirements are more stringent, the standard from the method or regulation shall be followed).	☹ 🗁				🔔
D.3 Are the quality control protocols specified by the laboratory's method manual followed by all analysts?	☹ 🗁				🔔
D.3 Are all essential quality control measures in Appendix D incorporated in the lab's method manual?	☹ 🗁				🔔
D.3 Are all quality control measures assessed and evaluated on an on-going basis?	☹ 🗁				🔔
5.9.4.1.d, D.3.8.b.6.i Are temperatures of incubators and water baths recorded twice daily?	☹ 🗁				🔔
5.9.4.1.d Is the following support equipment associated with microbiological testing checked with NIST traceable materials (where possible) a. ___ pH meter b. ___ Balance(s) c. ___ Conductivity meter d. ___ Refrigerator(s) for sample storage and/or media storage e. ___ Incubators f. ___ Water baths	☹ 🗁				🔔
5.11.3.a.2 Has the laboratory checked samples for proper preservation (e.g. pH, absence of free chlorine, temperature) prior to or during sample preparation or analysis. Note: Holding times are 30 hours for drinking water samples & 6 hours for wastewater samples? - 8 hours for source water.	☹ 🗁				🔔
D.3.1.a Does the laboratory demonstrate that the equipment, media and reagents have not been contaminated through sampling handling, preparation or environmental exposure?	☹ 🗁				🔔
D.3.1.a.1 A sterility is analyzed for each commercial lot of selective media or batch of media prepared in the lab prior to the use of the media?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.3.1.a.2 For each filtration series in the filtration technique, does the laboratory prepare at least one beginning and one ending sterility check?	☹ 🗁				🔔
D.3.1.a.2 When an interruption of more than 30 minutes occurs, are the filtration funnels re-sterilized?	☹ 🗁				🔔
D.3.1.a.3 For pour plate technique, are sterility blanks of the medium made by pouring, at a minimum, one uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared in the laboratory?	☹ 🗁				🔔
D.3.1.a.4 Are sterility checks on sample containers performed on at least one container for each lot of purchased, pre-sterilized containers?	☹ 🗁				🔔
D.3.1.a.4 For containers prepared and sterilized in the laboratory, is a sterility check performed on one container per sterilized batch with non-selective growth media?	☹ 🗁				🔔
D.3.1.a.5 Is a sterility blank performed on each batch of dilution water prepared in the laboratory and on each batch of pre-prepared, ready-to-use dilution water with non-selective growth media?	☹ 🗁				🔔
D.3.1.a.6 Is at least one filter from each new lot of membrane filters checked for sterility with non-selective growth media?	☹ 🗁				🔔
D.3.1.b.1 Is each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) and each batch of medium prepared in the laboratory tested with at least one pure culture of a known positive reaction prior to first use of the medium?	☹ 🗁				🔔
D.3.1.c Is each pre-prepared, ready-to-use lot of selective medium (including chromofluorogenic reagent) and each batch of selective medium prepared in the laboratory analyzed with one or more known negative culture controls, i.e. non-target organisms, as appropriate to the method prior to first use?	☹ 🗁				🔔
D.3.2 For test methods that specify colony counts such as membrane filter or plated media, are duplicate counts performed monthly on one positive sample, for each month that the test is performed?	☹ 🗁				🔔
D.3.2 If the lab has two or more analysts, does each analyst count typical colonies on the same plate for each month the test is performed?	☹ 🗁				🔔
D.3.2 Are counts within 10% difference considered to be acceptable?	☹🗁				🔔
D.3.2 In a laboratory with only one microbiology analyst, is the same plate counted twice by the analyst for each month the test is performed, with no more than 5% difference between the counts considered acceptable?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.3.3.a Is the Laboratory required to demonstrate proficiency with the test method prior to first use by [ ] comparison to a method already approved for use in the laboratory, or by [ ] analyzing a minimum of ten spiked samples whose matrix is representative of those normally submitted to the laboratory, or by [ ] analyzing and passing one proficiency test series provided by an approved proficiency sample provider?	☹ 🗁				🔔
D.3.3.a Does the laboratory maintain this documentation as long as the method is in use and for at least 5 years past the date of last use?	☹ 🗁				🔔
D.3.3.b To evaluate the ability of the laboratory to produce acceptable data, does the laboratory participate in the Proficiency Test programs (interlaboratory) identified by NELAP (5.4.2j or 5.5.3.4)?	☹ 🗁				🔔
D.3.4.a Are all growth and recovery media checked to assure that the target organisms respond in an acceptable and predictable manner?	☹ 🗁				🔔
D.3.4.b To ensure that analysis results are accurate, is target organism identity verified as specified in the method, e.g. by use of the completed test, or by use of secondary verification tests such as a catalase test?	☹ 🗁				🔔
D.3.5 Are the calculations, data reduction and statistical interpretations specified by each method followed?	☹ 🗁				🔔
D.3.6 Does the laboratory ensure that the quality of the reagents and media used is appropriate for the test concerned?	☹ 🗁				🔔
D.3.6.a Is culture media prepared in the laboratory from [ ] commercial dehydrated powders, [ ] purchased ready to use, or [ ] prepared from different chemical ingredients if not available commercially or specified by the method?	☹ 🗁				🔔
D.3.6.b Are reagents and commercial dehydrated powders used within the shelf life of the product and documented according to 5.10.5 (**5.10-27** through **5.10-30**)?	☹ 🗁				🔔
D.3.6.c Is distilled water, deionized water or reverse osmosis produced water free from bactericidal and inhibitory substances used in the preparation of media solutions and buffers?	☹ 🗁				🔔
D.3.6.c Where required by the method, is the quality of the water (such as chlorine residual, specific conductance, and heterotrophic bacteria plate count) monitored on a monthly frequency, when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.3.6.c is analysis for metals and the Bacteriological Water Quality Test (to determine presence of toxic agents or growth promoting substances) performed annually? (An exception to performing the Bacteriological Water Quality Test shall be given to laboratories that can supply documentation to show that their water source meets the criteria, as specified by the method, for Type I or Type II reagent water.)	☹ 🗁				🔔
D.3.6.c Do the results of these analyses meet the specifications of the required method and are records of analyses maintained for five years?	☹ 🗁				🔔
D.3.6.d Are media, solutions and reagents prepared, used and stored according to a documented procedure following the manufacturer's instructions or the test method.	☹ 🗁				🔔
D.3.6.d Does documentation for media prepared in the laboratory include: a.___ Date of preparation, b.___ Preparer's initials, c.___ Type and amount of media prepared, d.___ Manufacturer and lot number, e.___ Final pH of the media, and f.___ Expiration date	☹ 🗁				🔔
D.3.6.d Does documentation for media purchased pre-prepared, ready-to-use include: a.___ Manufacturer, b.___ Lot number, c.___ Type and amount of media received, d.___ Date of receipt, e.___ Expiration date of the media, and f.___ pH of the media	☹ 🗁				🔔
D.3.7.a In order to ensure identity and traceability, does the laboratory use reference cultures of microorganisms obtained from a recognized national collection, organization, or manufacturer recognized by the NELAP Accrediting Authority?	☹ 🗁				🔔
D.3.7.a Are Microorganisms [ ] single use preparations or [ ] cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism?	☹ 🗁				🔔
D.3.7.a.1 Are reference cultures [ ] revived (if freeze-dried) or [ ] transferred from slants and subcultured once to provide reference stocks?	☹ 🗁				🔔
D.3.7.a.1 Are the reference stocks preserved by a technique that maintains the desired characteristics of the strains?	☹ 🗁				🔔
D.3.7.a.1 Are reference stocks used to prepare working stocks for routine work?	☹🗁				🔔
D.3.7.a.1 The laboratory does not re-freeze or re-use reference stocks after they are thawed?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.3.7.a.2 Are working stocks sub-cultured no more than 5 times?	☹ 🗁				🔔
D.3.7.a.2 Are working stocks not sub-cultured to replace reference stocks?	☹ 🗁				🔔
D.3.8.a Are walls, floors, ceilings, and work surfaces non-absorbent and easy to clean and disinfect?	☹ 🗁				🔔
D.3.8.a Are work surfaces adequately sealed?	☹🗁				🔔
D.3.8.a Does the laboratories provide sufficient storage space?	☹ 🗁				🔔
D.3.8.a Is the laboratory clean and free from dust accumulation?	☹ 🗁				🔔
D.3.8.a Does the laboratory prohibit plants food and drink in the laboratory work area?	☹🗁				🔔
D.3.8.b.1 Are the temperature measurement devices such as liquid-in-glass thermometers, thermocouples, and platinum resistance thermometers used in incubators, autoclaves and other equipment the appropriate quality needed to achieve the specification in the test method?	☹ 🗁				🔔
D.3.8.b.1 Are the graduations of the temperature measuring devices appropriate for the required accuracy of measurement?	☹ 🗁				🔔
D.3.8.b.1 Are the devices temperature calibration traceable to national or international standards at least annually?	☹ 🗁				🔔
D.3.8.b.2.i Is the performance of each autoclave initially evaluated by establishing its functional properties and performance, for example heat distribution characteristics with respect to typical uses?	☹ 🗁				🔔
D.3.8.b.2.i Do autoclaves meet specified temperature tolerances?	☹🗁				🔔
D.3.8.b.2.i Are pressure cookers not used for sterilization of growth media?	☹🗁				🔔
D.3.8.b.2.ii Is sterilization demonstrated by the use of continuous temperature recording devices or through the use of a maximum registering thermometer with every cycle?	☹ 🗁				🔔
D.3.8.b.2.ii Are appropriate biological indicators used at least once each month of use to determine effective sterilization?	☹ 🗁				🔔
D.3.8.b.2.ii Is temperature sensitive tape used with the contents of each autoclave run to indicate that the autoclave contents have been processed?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.38.b.2.iii Are records of autoclave operations include: a.___ Date, b.___ Contents, c.___ Maximum temperature reached, pressure, d.___Time in sterilization mode, e.___Total run time (may be recorded as time in and time out) and f.___ Analysts initials	☹ 🗁				🔔
D.3.8.b.2.iv Is autoclave maintenance, either internally or by service contract, performed annually?	☹ 🗁				🔔
D.3.8.b.2.iv Does the annual maintenance of the autoclave include a pressure check and calibration of temperature device?	☹ 🗁				🔔
D.3.8.b.2.iv Are records of the maintenance maintained in equipment logs?	☹ 🗁				🔔
D.3.8.b.2.v Is the autoclave mechanical timing device checked quarterly against a stopwatch and is the actual time elapsed documented?	☹ 🗁				🔔
D.3.8.b.3.i Is volumetric equipment with movable parts such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes calibrated quarterly?	☹ 🗁				🔔
D.3.8.b.3.ii Is volumetric equipment such as filter funnels, bottles, non-class A glassware, and other marked containers calibrated once per lot prior to first use?	☹ 🗁				🔔
D.3.8.b.3.iii Is the volume of the disposable volumetric equipment such as sample bottles, disposable pipettes, and micropipette tips checked once per lot?	☹ 🗁				🔔
D.3.8.b.4 Do UV instruments, used for sanitization, get tested quarterly for effectiveness with an appropriate UV light meter or by plate count agar spread plates?	☹ 🗁				🔔
D.3.8.b.4 Are bulbs replaced if output is less than 70% of original for light tests or if count reduction is less than 99% for a plate containing 200 to 300 organisms?	☹ 🗁				🔔
D.3.8.b.5 Is support equipment calibrated according to the method specified requirements? (Note this includes conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments)	☹ 🗁				🔔
D.3.8.b.6.i Has the stability and uniformity of temperature distribution and time required after test sample addition to re-establish equilibrium conditions in incubators and water baths been established?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.3.8.b.6.i Is the temperature of incubators and water baths documented twice daily, at least four hours apart, on each day of use?	☹ 🗁				🔔
D.3.8.b.6.ii Are ovens used for sterilization checked for sterilization effectiveness monthly with appropriate biological indicators?	☹ 🗁				🔔
D.3.8.b.6.ii Are records maintained for each oven cycle that includes: a.___ Date, b.___ Cycle time, c.___ Temperature, d.___ Contents and e.___ Analyst's initials.	☹ 🗁				🔔
D.3.8.b.7.i Does the laboratory have a documented procedure for washing labware, if applicable?	☹ 🗁				🔔
D.3.8.b.7.i Are detergents designed for laboratory use used?	☹ 🗁				🔔
D.3.8.b.7.ii Is glassware made of borosilicate or other non-corrosive material, free of chips and cracks, and does it have readable measurement marks?	☹ 🗁				🔔
D.3.8.b.7.iii Does the laboratory test glassware for possible presence of residues which may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test annually, and each time the lab changes the lot of detergent, personnel, or washing procedures?	☹ 🗁				🔔
D.3.8.b.7.iv Is each batch of washed glassware tested for possible acid or alkaline residue by testing one piece of glassware with a suitable pH indicator such as bromthymol blue, with a record of the test being maintained?	☹ 🗁				🔔

APPENDIX D.4 - Radiochemical Analysis Detailed Method Review					
The findings and observations recorded here are based upon the evaluation of the following records:					
Relevant Aspect of Standards	**Reference**	**Y**	**N**	**N/A**	**Comments**
5.1.b, 5.9.4.2 Does the laboratory demonstrate that it meets all requirements contained in a mandated test method or by regulation, even if the requirement is more stringent than the corresponding NELAC standard? (If it is unclear which requirements are more stringent, the standard from the method of regulation shall be followed)	☹ 🗁				🔔
D.4 Are the quality control protocols specified by the laboratory's method manual followed by all analysts?	☹ 🗁				🔔
D.4 Are all essential quality control measures in Appendix D incorporated in the lab's method manual?	☹ 🗁				🔔
D.4 Are all quality control measures assessed and evaluated on an on-going basis?	☹🗁				🔔
D.4 Does the laboratory have procedures for developing acceptance/rejection criteria where no method or regulatory criteria exists?	☹ 🗁				🔔
D.4.1.a.1 Are method blanks, analyzed at a frequency of one per preparation batch, used to assess batch acceptance?	☹ 🗁				🔔
D.4.1.a.1 Is the method blank result assessed against the specific acceptance criteria specified in the laboratory method manual?	☹ 🗁				🔔
D.4.1.a.1 When the method blank acceptance criteria are not met, are the corrective action and contingencies specified in the laboratory method manual followed and are results reported with appropriate data qualifying codes?	☹ 🗁				🔔
D.4.1.a.1 Does the laboratory note the occurrence of a failed method blank and the actions taken in the laboratory report?	☹ 🗁				🔔
D.4.1.a.2 In the case of gamma spectrometry where the sample matrix is simply aliquoted into a calibrated counting geometry, is the method blank prepared from a similar counting geometry that is empty or filled to similar volume with ASTM Type II water used to partially simulate gamma attenuation due to a sample matrix?	☹ 🗁				🔔
D.4.1.a.3 Is method blank result not subtracted from the sample results in the associated preparation or analytical batch unless permitted by test method or program?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.4.1.a.3 If a correction factor such as instrument background, analyte presence in tracer, reagent impurity, peak overlap or calibration blank is applied, is it applied to all analyzed samples, both program/project submitted and internal QC samples?					
D.4.1.a.4 Is the method blank prepared with similar aliquot size to that of the routine samples for analysis?					
D.4.1.a.4 Are the method blank result and acceptance criteria calculated in a manner that compensates for sample results based upon differing aliquot size?					
D.4.1.b.1 Is a Laboratory Control Samples (LCS) analyzed at a frequency of one per preparation batch?					
D.4.1.b.1 Are the results of the analysis of the LCS used as one of the quality control measures to be used to assess batch acceptance?					
D.4.1.b.1 Is the laboratory control sample result assessed against the specific acceptance criteria specified in the laboratory method manual?					
D.4.1.b.1 When the specified laboratory control sample acceptance criteria is not met is the specified corrective action and contingencies followed?					
D.4.1.b.1 Is the occurrence of a failed laboratory control sample acceptance criteria and the actions taken noted in the laboratory report?					
D.4.1.b.2 Is a Matrix Spike analyzed at a frequency of one per preparation batch for those methods which do not utilize an internal standard or carrier and for which there is a physical or chemical separation process and where there is sufficient sample to do so? (Note: the exceptions are gross alpha, gross beta, and tritium which require matrix spikes for aqueous samples.)					
D.4.1.b.2 Are the results of the matrix spike analysis one of the quality control measures used to assess batch acceptance?					
D.4.1.b.2 Is the matrix spike result assessed against the specific acceptance criteria specified in the laboratory method manual?					
D.4.1.b.2 When the specified matrix spike acceptance criteria is not met, is the specified corrective action and contingencies followed?					
D.4.1.b.2 Is the occurrence of a failed matrix spike acceptance criteria and the actions taken noted in the laboratory report?					
D.4.1.b.2 Is the lack of sufficient sample aliquot size to perform a matrix spike analysis noted in the laboratory report?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.4.1.b.3 Is the activity of the laboratory control sample (1) greater than two to ten times the detection limit or (2) at a level comparable to that of routine samples if the sample activities are expected to exceed 10 time the detection limit?					
D.4.1.b.4 Is the activity of the matrix spike analyte(s) greater than ten times the detection limit?					
D.4.1.b.5 Are the laboratory standards used to prepare the LCS and matrix spike from a source independent of the laboratory standards used for instrument calibration?					
D.4.1.b.6 When a radiochemical method, other than gamma spectroscopy, has more than one reportable analyte isotope (e.g. isotopic uranium: U-234, -235, and -238) is one of the analyte isotopes included in the laboratory control or matrix spike sample at the indicated activity level?					
D.4.1.b.6 Where more than one analyte isotope is present in the LCS or matrix spike above the specified detection limit is the activity level of each analyte assessed against the specified acceptance criteria?					
D.4.1.b.7 Where gamma spectrometry is used to identify and quantitate more than one analyte isotope does the LCS and matrix spike contain isotopes that represent the low (e.g. americium-241), medium (e.g. cesium-137) and high (e.g. cobalt-60) energy range of the analyzed gamma spectra? (The isotopes need not exactly bracket the calibrated energy range or the range over which isotopes are identified and quantitated.)					
D.4.1.b.8 Is the laboratory control sample prepared using a similar aliquot size to that of the routine samples for analysis?					
D.4.1.c.1 For those methods that utilize a tracer (i.e. internal standard), is each sample tracer recovery calculated and reported?					
D.4.1.c.1 Is the tracer recovery for each sample results one of the quality control measures used to assess the associated sample result acceptance?					
D.4.1.c.1 Is the tracer recovery assessed against the specific acceptance criteria specified in the laboratory method manual?					
D.4.1.c.1 When the specified tracer recovery acceptance criteria is not met, are the specified corrective action and contingencies followed?					
D.4.1.c.1 Is the occurrence of a failed tracer recovery acceptance criteria and the actions taken noted in the laboratory report?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.4.1.c.2 For those methods that utilize a carrier (i.e. internal standard), is each sample carrier recovery calculated and reported?					
D.4.1.c.2 Is the carrier recovery for each sample one of the quality control measures used to assess the associated sample result acceptance?					
D.4.1.c.2 Is the carrier recovery assessed against the specific acceptance criteria specified in the laboratory method manual?					
D.4.1.c.2 When the specified carrier recovery acceptance criteria is not met, is the specified corrective action and contingencies followed?					
D.4.1.c.2 Is the occurrence of a failed carrier recovery acceptance criteria and the actions taken noted in the laboratory report?					
D.4.2.a Are replicates analyzed at a frequency of one per preparation batch where there is sufficient sample to do so?					
D.4.2.a Are the results of replicate analysis one of the quality control measures used to assess batch acceptance?					
D.4.2.a Is the replicate result assessed against the specific acceptance criteria specified in the laboratory method manual?					
D.4.2.a When the specified replicate acceptance criteria is not met, are the specified corrective action and contingencies followed?					
D.4.2.a Does the corrective action take into consideration the fact that sample inhomogeneity may be a cause of the failed replicate acceptance criteria?					
D.4.2.a Is the occurrence of a failed replicate acceptance criteria and the actions noted in the laboratory report?					
D.4.2.b For low level samples (less than approximately three times the detection limit), does the laboratory analyze duplicate laboratory control samples or a replicate matrix spike (matrix spike and matrix spike duplicate) to determine reproducibility within a preparation batch?					
D.4.3.a, 5.10.2.1.a The Initial Demonstration of is performed initially (prior to the analysis of any samples) and with a significant change in instrument type, personnel or method?					
D.4.3.b Are the results of proficiency test sample analysis used by the laboratory to evaluate the ability of the laboratory to produce accurate data?					
D.4.4.a.1 Does the laboratory calibrate radiochemistry analytical instruments when purchased, when the instrument is services, when the instrument is moved, and when the instrument setting(s) have been changed?					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.4.4.a.2 Does the laboratory perform instrument calibration with reference standards as defined in section D.4.7.a, and do the standards have the same general characteristics (i.e., geometry, homogeneity, density, etc.) as the associated samples?					
D.4.4.a.3 Is the frequency of calibration specified in the laboratory method manual or test method?					
D.4.4.a.3 Is a specific frequency (e.g., monthly) or observations from associated control or tolerance charts specified in the laboratory method manual?					
D.4.4.b Are calibration verification checks performed using appropriate check sources and monitored with control charts or tolerance charts to ensure that the instrument is operating properly and that the calibration has not changed?					
D.4.4.b Is the same check source used in the preparation of the tolerance chart or control chart at the time of calibration used in the calibration verification of the instrument?					
D.4.4.b Does the check sources provide adequate counting statistics for a relatively short count time?					
D.4.4.b Is the check source sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel?					
D.4.4.b For alpha and gamma spectroscopy systems, does the instrument calibration verification include checks on the counting efficiency and the relationship between channel number and alpha or gamma ray energy?					
D.4.4.b.1 For gamma spectroscopy systems, are the calibration verification checks for efficiency and energy calibration performed on a day of use basis along with performance checks on peak resolution?					
D.4.4.b.2 For alpha spectroscopy systems, are the calibration verification check for energy calibration performed on a weekly basis, and the performance check for counting efficiency performed on at least a monthly basis?					
D.4.4.b.3 For gas-proportional and liquid scintillation counters, is the calibration verification check for counting efficiency performed on a day of use basis? (Note: Verification of instrument calibration does not directly verify secondary calibrations, e.g., the mass efficiency curve or the quench curve)					

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.4.4.b.4 For scintillation counters, is the calibration verification check for counting efficiency performed on a day of use basis?	☹ 🗁				🔔
D.4.4.c Are background measurements made on a regular basis?	☹ 🗁				🔔
D.4.4.c Are background measurements monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required data quality objectives?	☹ 🗁				🔔
D.4.4.c Are background measurements subtracted from the total measured activity in the determination of the sample activity?	☹ 🗁				🔔
D.4.4.c.1 For gamma spectroscopy systems, are background measurements performed on at least a monthly basis?	☹ 🗁				🔔
D.4.4.c.2 For alpha spectroscopy systems, are background measurements performed on at least a monthly basis?	☹ 🗁				🔔
D.4.4.c.3 For gas-proportional counters, are background measurements performed on a weekly basis?	☹ 🗁				🔔
D.4.4.c.4 For scintillation counters, are background calibration measurements performed on a day of use basis?	☹ 🗁				🔔
D.4.5.a Are detection limits determined prior to sample analysis and redetermined each time there is a significant change in the test method or instrument type?	☹ 🗁				🔔
D.4.5.b Are the procedures for the determination of detection limits documented and consistent with mandated methods or regulations?	☹ 🗁				🔔
D.4.6.a Are the procedures for data reduction consistent with Section 5.10.6 of the NELAC standard?	☹ 🗁				🔔
D.4.6.b Is each result reported with the associated measurement uncertainty, and are the procedures for determining measurement uncertainty documented and consistent with mandated methods and regulations?	☹ 🗁				🔔
D.4.7.a Does the laboratory's quality control program establish and maintain provisions for radionuclide standards?	☹ 🗁				🔔
D.4.7.a.1 Are the reference standards that are used obtained from the National Institute of Standards and Technology (NIST), EPA, or suppliers who participate in supplying NIST standards or NIST traceable radionuclides?	☹ 🗁				🔔
D.4.7.a.1 Are any reference standards purchased outside the United States traceable back to each country's national standards laboratory?	☹ 🗁				🔔

Relevant Aspect of Standards	Reference	Y	N	N/A	Comments
D.4.7.a.1 Do commercial suppliers of reference standards conform to ANSI N42.22 to assure the quality of their products?	☹ 🗁				🔔
D.4.7.a.2 Are reference standards accompanied with a certificate of calibration whose content is as described in ANSI N42.22 – 1995, Section 8, Certificates?	☹ 🗁				🔔
D.4.7.a.3 Does the laboratory consult with the supplier if the lab's verification of the activity of the reference traceable standard indicates a noticeable deviation from the certified value?	☹ 🗁				🔔
D.4.7.a.3 The laboratory does not use a value for a standard other than the decay corrected certified value?	☹ 🗁				🔔
D.4.7.b Are all reagents used analytical reagent grade or better?	☹ 🗁				🔔
D.4.8.a Does the laboratory establish written procedures to minimize the possibility of cross-contamination between samples?	☹ 🗁				🔔
D.4.8.b For gamma spectrometry systems, are background check measurements performed each day of use?	☹ 🗁				🔔
D.4.8.c For alpha spectrometry systems, are background check measurements performed except when using the electro-plating method of sample preparation?	☹ 🗁				🔔
D.4.8.d For gas-proportional counter systems, are background check measurements performed each day of use?	☹ 🗁				🔔